NOTE: Where it is feasible, a syllabus (headnote) will be released, as is being done in connection with this case, at the time the opinion is issued. The syllabus constitutes no part of the opinion of the Court but has been prepared by the Reporter of Decisions for the convenience of the reader. See *United States* v. *Detroit Lumber Co.*, 200 U.S. 321, 337.

# SUPREME COURT OF THE UNITED STATES

## Syllabus

## WEINBERGER ET AL. *v.* HYNSON, WESTCOTT & DUNNING, INC.

CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

No. 72-394. Argued April 17, 1973—Decided June 18, 1973*

The Federal Food, Drug, and Cosmetic Act of 1938, as amended in 1962, establishes a system of premarketing clearance for drugs and prohibits in § 505 (a) the introduction into commerce of any "new drug" unless a new drug application (NDA) filed with the Food and Drug Administration (FDA) was *effective* with respect to such drug. Under the Act procedures were established for filing "new drug" applications not only for the *safety* of drugs but for their *efficacy* as well. Standards were provided under which, after notice and hearing, FDA could refuse to allow an NDA to become effective, or could suspend an NDA in effect on the basis of new evidence that the drug was not effective. FDA is directed to refuse approval of an NDA and to withdraw prior approval if "substantial evidence" (§ 505 (d)) that the drug is effective for its intended use is lacking. All NDA's "effective" prior to 1962 were deemed "approved" and manufacturers were given two years to develop substantial evidence of effectiveness during which previously approved NDA's could not be withdrawn by FDA for the drug's lack of effectiveness. The 1962 Act also contained a "grandfather" clause exempting from the effectiveness requirements any drug which on the day preceding enactment (1) was commercially used or sold in the United States, (2) was not a "new drug" as defined in the 1938 Act, and (3) "was not covered by an effective application" for a new drug under the 1938 Act. The FDA had permitted more than 9,000 NDA's to become effective between 1938 and 1962, of which some 4,000 were still on the market. Additionally, manufacturers have marketed thousands of

*Together with No. 72-414, *Hynson, Westcott & Dunning, Inc.* v. *Weinberger et al.*, also on certiorari to the same court.

Syllabus

"me-too" drugs without applying for clearance, drugs similar or identical to drugs with effective NDA's, marketed in reliance on the "pioneer" drug application approved by the FDA. To aid it in fulfilling the statutory mandate to review all marketed drugs, whether or not previously approved, for their efficacy, the FDA retained the National Academy of Sciences-National Research Council (NAS–NRC) to create expert panels to review by class the efficacy of each approved drug. Holders of NDA's were invited to furnish the panels with the best available data to establish efficacy and the FDA announced that it would apply NAS–NRC efficacy findings to all drugs, including the "me-too" drugs. Respondent in No. 72–394 (Hynson) had filed an application for a drug called Lutrexin under the 1938 Act. The FDA informed Hynson that the studies submitted with the application were not sufficiently well controlled to justify the claims of effectiveness, but allowed the application to become effective since the 1938 Act permitted evaluation of a new drug solely on the basis of its safety. When the 1962 amendments became effective Hynson submitted evidence of the efficacy of the drug, but the NAS–NRC panel reported that Hynson had not satisfied the requirements. Notice of an intention to withdraw approval of the NDA's covering the drug was given. Before the hearing, Hynson brought suit in the District Court for a declaratory judgment that the drug was exempt from the *efficacy* review provisions of the 1962 Act, or that there was no lack of substantial evidence of the drug's efficacy. Petitioners' motion to dismiss was granted. The Court of Appeals reversed, holding that while the drug was not exempt, Hynson was entitled to a hearing on the substantial evidence issue. No. 72–414 is a cross-petition by Hynson from the judgment of the Court of Appeals, which suggested that only a district court has authority to determine whether Lutrexin is a "new drug." While Hynson agrees that the Commissioner has authority to determine new drug status in proceedings to withdraw approval of the product's NDA, some manufacturers, parties to other suits in this group of cases, advance the contrary view. *Held:*

1. The 1962 Amendments and the regulations issued thereunder, which express well-established principles of scientific investigation, in their reduction of the "substantial evidence" standard to detailed guidelines for the protection of the public, make the FDA's so-called administrative summary judgment procedure appropriate. Pp. 5–9.

Syllabus

2. FDA's procedure, whereby it will not provide a formal hearing when it is apparent at the threshold that the applicant has not tendered *any* evidence which *on its face* meets the statutory standards as particularized by the regulations, is valid. *United States* v. *Storer Broadcasting Co.,* 351 U. S. 192, *FPC* v. *Texaco,* 377 U. S. 33. Pp. 9–11.

3. In No. 72–394, the Court of Appeals' holding that Hynson was entitled to a hearing on whether its submission of evidence satisfied its threshold burden of providing "substantial evidence" is affirmed. Pp. 11–12.

4. The heart of the statutory procedure is the grant of primary jurisdiction to the FDA, subject to judicial review when administrative remedies are exhausted. Pp. 12–17.

5. Although a drug can be "generally recognized" by experts as effective for intended use within the meaning of the Act only when that expert consensus is founded upon "substantial evidence," any ruling on Lutrexin's "new drug" status is premature, and must await the outcome of the hearing on whether Hynson submitted "substantial evidence," as held in No. 72–394 (item 3, *supra*). Pp. 17–21.

6. Lutrexin is not exempt under the "grandfather" provisions of the 1962 Act, as held by the FDA and the Court of Appeals, and their construction accords with the legislative history which suggests that the exemption is afforded only for drugs that never had been subject to new drug regulation. Pp. 21–23.

461 F. 2d 215, affirmed as modified.

DOUGLAS, J., delivered the opinion of the Court, in which BURGER, C. J., and WHITE, MARSHALL, BLACKMUN, and REHNQUIST, JJ., joined. POWELL, J., filed an opinion concurring in the result as to Part I and joining in Part II of the Court's opinion. BRENNAN, J., took no part in the consideration or decision of the case. STEWART, J., took no part in the decision of the case.

# SUPREME COURT OF THE UNITED STATES

Nos. 72–394 AND 72–414

Casper W. Weinberger, Secretary of Health, Education, and Welfare, et al., Petitioners,
72–394 *v.*
Hynson, Westcott and Dunning, Incorporated.

Hynson, Westcott and Dunning, Incorporated, Petitioner,
72–414 *v.*
Casper W. Weinberger, Secretary of Health, Education, and Welfare, et al.

On Writs of Certiorari to the United States Court of Appeals for the Fourth Circuit.

[June 18, 1973]

MR. JUSTICE DOUGLAS delivered the opinion of the Court.

These cases, together with *Weinberger* v. *Bentex Pharmaceuticals, Inc., post,* at —, *CIBA Corp.* v. *Weinberger, post,* at —, and *USV Pharmaceutical Corp.* v. *Weinberger, post,* at —, all here on certiorari, raise a series of questions under the 1962 amendments[1] to the Federal Food, Drug, and Cosmetic Act of 1938. 52 Stat. 1040. The 1938 Act, which established a system of premarketing clearance for drugs, prohibited the introduction into commerce of any "new drug" unless a new drug application (NDA) filed with the Food and Drug Administration

[1] Drug Amendments of 1962 (Harris-Kefauver Act), 76 Stat. 780, amending 21 U. S. C. § 301 *et seq.*

(FDA)[2] was effective with respect to that drug. § 505 (a). 52 Stat. 1052. Under the 1938 Act a "new drug" was one not generally recognized by qualified experts as safe for its intended use. § 201 (p)(1). The Government could sue to enjoin violations, prosecute criminally, and seize and condemn the articles. §§ 301 (d), 302 (a), 303, 304. The Act established procedures for filing new drug applications, § 505 (b), and provided standards under which, after notice and hearing, FDA could refuse to allow an NDA to become effective, §§ 505 (c) and (d), or could suspend an NDA in effect on the basis of new evidence that the drug was unsafe. § 505 (e). Orders denying or suspending an NDA could be reviewed in a district court on the administrative record. § 505 (h).

The 1962 Act amended § 201 (p)(1) of the 1938 Act to define a "new drug" as a drug not generally recognized among experts as *effective* as well as safe for its intended uses. 21 U. S. C. § 321 (p)(1). A new drug, as now defined, still may not be marketed unless an NDA is in effect. FDA is now directed to refuse approval of an NDA and to withdraw any prior approval if "substantial evidence"[3] that the drug is effective for its intended use is

---

[2] The Act originally provided for filing applications with the Secretary of Agriculture, but his functions were assigned to the FDA. The FDA is now part of the Department of Health, Education, and Welfare (HEW), and the Secretary of HEW has delegated his responsibilities under the Federal Food, Drug, and Cosmetic Act to the Commissioner of Food and Drugs. 21 CFR § 2.120.

[3] "Substantial evidence" was defined to mean "evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have . . . ." 21 U. S. C. § 355 (d).

lacking. 21 U. S. C. §§ 355 (d) and (e). Thus, the basic clearance system, requiring FDA approval of an NDA before a "new drug" may be lawfully marketed, was continued, except that FDA now either must approve or disapprove an application within 180 days. 21 U. S. C. § 355 (c). (Under the 1938 Act an application automatically became effective if it was not disapproved.) Judicial review was transferred to the courts of appeal. 21 U. S. C. § 355 (h).

Since the Act as amended requires affirmative agency approval, all NDAs "effective" prior to 1962 were deemed "approved" under the new definition, and manufacturers were given two years to develop substantial evidence of effectiveness during which previously approved NDAs could not be withdrawn by FDA for a drug's lack of effectiveness.[4] The 1962 amendments also contain a "grandfather" clause exempting from the effectiveness requirements any drug which on the day preceding enactment (1) was commercially used or sold in the United States, (2) was not a "new drug" as defined in the 1938 Act (it being generally recognized as safe) and (3) "was not covered by an effective application" for a new drug under the 1938 Act.[5]

Between 1938 and 1962 FDA had permitted 9,457 NDAs to become effective. Of these some 4,000 were still on the market. In addition, there were thousands of drugs which manufacturers had marketed without applying to the FDA for clearance. These drugs, known as "me-toos," are similar to or identical with drugs with effective NDAs and are marketed in reliance on the "pioneer" drug application approved by the FDA. In some cases, a manufacturer obtained an advisory opinion

---

[4] Drug Amendments of 1962, §§ 107 (c)(2) and (c)(3)(B), 76 Stat. 788–789, note following 21 U. S. C. § 321 (1970 ed.).

[5] *Id.*, § 107 (c)(4).

letter from the FDA that its product was generally recognized among experts as safe.

To aid in its task of fulfilling the statutory mandate to review all marketed drugs for their threapeutic efficacy, whether or not previously approved, the FDA retained the National Academy of Sciences-National Research Council (NAS–NRC) to create expert panels to review by class the efficacy of each approved drug. Holders of NDAs were invited to furnish the panels with the best available data to establish the effectiveness of their drugs.[6] The panels reported to FDA; and on January 23, 1968, the FDA announced its policy of applying the NAS–NRC efficacy findings to all drugs, including the related "me-too" drugs.[7]

## I

Respondent in No. 394, Hynson, Wescott and Dunning, Inc., had filed an application under the 1938 Act for a drug called Lutrexin, recommended by Hynson for use in the treatment of premature labor, threatened and habitual abortion, and dysmenorrhea. FDA informed Hynson that Hynson's studies submitted with the application were not sufficiently well controlled to justify the claims of effectiveness and urged Hynson not to represent the drug as useful for threatened and habitual abortion. But the FDA allowed the application to become effective, since the 1938 Act permitted evaluation of a new drug solely on the grounds of its *safety*. Before the 1962 amendments

---

[6] 31 Fed. Reg. 9426.

[7] The FDA has recently adopted a regulation declaring the manner in which Drug Efficacy Study Implementation (DESI) Notices and Notices of Opportunity for Hearing apply to identical, related, and similar drugs. Any person with an interest in such drugs are provided an opportunity for hearing on any proposed withdrawal of NDA approval for the basic or pioneer drug. 37 Fed. Reg. 23185, adding § 130.40 to 21 CFR.

Hynson filed an application for a related drug which the FDA, again on the basis of the test of *safety*, allowed to become effective. When the 1962 amendments became effective and NAS–NRC undertook to appraise the efficacy of drugs theretofore approved as safe, Hynson submitted a list of literature references, a copy of an unpublished study, and a representative sample testimonial letter on behalf of Lutrexin. The panel of NAS–NRC working in the relevant field reported to FDA that Hynson's claims for effectiveness of the drug were either inappropriate or unwarranted in the absence of submission of further appropriate documentation. At the invitation of the Commissioner on Food and Drugs, Hynson submitted additional data. But the Commissioner concluded that this additional information was inadequate and published notice of his intention to withdraw approval of the NDAs covering the drug, offering Hynson the opportunity for a prewithdrawal hearing. Before the hearing could take place, Hynson brought suit in the District Court for a declaratory judgment that the drugs in question were exempt from the *efficacy* review provisions of the 1962 amendments or, alternatively, that there was no lack of substantial evidence of the drug's *efficacy*. The Government's motion to dismiss was granted, the District Court ruling that FDA had primary jurisdiction and that Hynson had failed to exhaust its administrative remedies.

While the District Court litigation was pending, FDA promulgated new regulations establishing minimal standards for "adequate and well-controlled investigations" and limiting the right to a hearing to those applicants who could proffer at least some evidence meeting those standards.[8] Although Hynson maintained that it was not subject to the new regulations because its initial request for a hearing predated their issuance, it renewed

---

[8] 35 Fed. Reg. 7251, amending 21 CFR §§ 130.12 (a) (5) and 130.14.

its request and submitted the material which it claimed constituted "substantial evidence" of Lutrexin's effectiveness. The Commissioner denied the request for a hearing and withdrew the NDA for Lutrexin. He ruled that Lutrexin is not exempt from the 1962 amendments and that Hynson had not submitted adequate evidence that Lutrexin is not a new drug or is effective. The Court of Appeals reversed, 461 F. 2d 215, holding that while the drugs in question were not exempt, Hynson was entitled to a hearing on the substantial evidence question.

Section 505 (e) [9] directs the FDA to withdraw approval of an NDA if the manufacturer fails to carry the burden of showing there is "substantial evidence" [10] respecting the *efficacy* of the drug. As the Court of Appeals says, "substantial evidence" was substituted for "preponderance" of the evidence. 461 F. 2d, at 220. The Act and the Regulations, in their reduction of that standard to detailed guidelines,[11] make the FDA's so-called administrative summary judgment procedure appropriate.

The general contours of "substantial evidence" are defined by § 505 (d) of the Act to include "evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by

---

[9] Section 505 (e) as amended, 21 U. S. C. § 355 (e), provides in relevant part:

"The Secretary shall, after due notice and opportunity for hearing to the applicant, withdraw approval of an application with respect to any new drug under this section if the Secretary finds . . . (3) on the basis of new information before him with respect to such drug, evaluated together with the evidence available to him when the application was approved, that there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling thereof; . . ."

[10] See n. 2, *supra*.

[11] 21 CFR § 130.12 (a)(5) as amended, 35 F. R. 7251, is set forth in relevant part in an Appendix to this opinion.

scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof." 21 U. S. C. § 355 (d). Acting pursuant to his "authority to promulgate regulations for the efficient enforcement" of the Act, § 701 (a), 21 U. S. C. § 371 (a), the Commissioner has detailed the "principles . . . recognized by the scientific community as the essentials of adequate and well-controlled clinical investigations. They provide the basis for the determination whether there is 'substantial evidence' to support the claims of effectiveness for 'new drugs' . . . ." 21 CFR § 130.12 (a)(5)(ii). They include a "plan or protocol" setting forth the objective of the study and an adequate method for selecting appropriate subjects,[12] explaining the methods of observation and steps taken to minimize bias, providing a comparison by one of four "recognized" methods of the results of treatment or diagnosis with a control, and summarizing the methods of analysis, including any appropriate statistical methods. *Id.*, § 130.12 (a)(5)(ii)(*a*). No investigation will be considered "adequate for approval of a new drug" unless the test drug is "standardized as to identity, strength, quality, and dosage form to give significance to the results of the investigation." *Id.*, § 130.12 (a)(5)(ii)(*b*). Finally, the regulation provides that "[u]ncontrolled studies or partially controlled studies are not acceptable as the sole basis for the approval of claims

[12] Subjects must be chosen so that they are "suitable for the purposes of the study," assigned to test groups in such a way as to minimize bias, and comparable in terms of "pertinent variables, such as age, sex, severity, or duration of disease, and use of drugs other than the test drug." 21 CFR § 130.12 (a)(5)(ii)(*a*)(2).

of effectiveness. Such studies, carefully conducted and documented, may provide corroborative support. . . . Isolated case reports, random experience, and reports lacking the details which permit scientific evaluation will not be considered." *Id.*, § 130.12 (a)(5)(ii)(*c*).

Lower courts have upheld the validity of these regulations,[13] and it is not disputed here that they express well-established principles of scientific investigation. Moreover, their strict and demanding standards, barring anecdotal evidence indicating that doctors "believe" in the efficacy of a drug, is amply justified by the legislative history. The hearings underlying the 1962 Act show a marked concern that impressions or beliefs of physicians, no matter how fervently believed, are treacherous.[14] Congress wrote in § 505 (d) in its definition of "substantial evidence" the requirement of "evidence consisting of adequate and well-controlled investigations." The Senate Report makes clear that an abrupt departure was being taken from old norms for marketing goods. There had been mounting concern over *efficacy* of drugs as well as their *safety*.[15] The Report stated: [16]

". . . a claim could be rejected if it were found,

[13] *Upjohn Co.* v. *Finch*, 422 F. 2d 944 (CA6); *Pharmaceutical Manufacturers Assn.* v. *Richardson*, 318 F. Supp. 301 (Del.). The FDA was enjoined from enforcing the regulations as originally issued on September 19, 1969, 34 Fed. Reg. 14596, on the grounds that the FDA had not complied with the notice requirements of the Administrative Procedure Act. *Pharmaceutical Manufacturers Assn.* v. *Finch*, 307 F. Supp. 858 (Del.). The regulations were reissued in their current form on May 8, 1970. 35 Fed. Reg. 7251.

[14] See Hearings on S. 1552 before the Subcomm. on Antitrust and Monopoly of the Senate Comm. on the Judiciary, 87th Cong., 1st Sess., pt. 1, at 195, 282, 411–412. Much of this aspect of the legislative background of the 1962 Act is reviewed in enlightening detail by Judge Latchum in *Pharmaceutical Manufacturers Assn.* v. *Richardson*, *supra*, at 306 *et seq.*

[15] S. Rep. No. 1744, 87th Cong., 2d Sess., pt. 2, at 1.

[16] *Id.*, at 6.

(a) that the investigations were not 'adequate'; (b) that they were not 'well controlled'; (c) that they had been conducted by experts not qualified to evaluate the effectiveness of the drug for which the application is made; or (d) that the conclusion drawn by such experts could not fairly and responsibly be derived from their investigations."

To be sure, the Act requires the FDA to give "due notice and opportunity for hearing to the applicant" before it can withdraw its approval of an NDA. § 505 (e), 21 U. S. C. § 355 (e). The FDA, however, by regulation, requires any applicant who desires a hearing to submit reasons "why the application . . . should not be withdrawn, together with a well-organized and full-factual analysis of the clinical and other investigational data he is prepared to prove in support of his opposition to the notice of opportunity for a hearing. . . . When it clearly appears from the data in the application and from the reasons and factual analysis in the request for the hearing that there is no genuine and substantial issue of fact . . . , *e. g.*, no adequate and well-controlled clinical investigations to support the claims of effectiveness," the Commissioner may deny a hearing and enter an order withdrawing the application based solely on this data. 21 CFR § 130.14 (b). What the agency has said, then, is that it will not provide a formal hearing where it is apparent at the threshold that the applicant has not tendered *any* evidence which *on its face* meets the statutory standards as particularized by the regulations.

The propriety of such a procedure was decided in *United States* v. *Storer Broadcasting Co.*, 351 U. S. 192, 205, and *Federal Power Commission* v. *Texaco*, 377 U. S. 33, 39. We said in *Texaco:*

"[T]he statutory requirement for a hearing under § 7 [of the Natural Gas Act] does not preclude the

> Commission from particularizing statutory standards through the rulemaking process and barring at the threshold those who neither measure up to them nor show reasons why in the public interest the rule should be waived." *Ibid.*

There can be no question that to prevail at a hearing an applicant must furnish evidence stemming from "adequate and well-controlled investigations." We cannot impute to Congress the design of requiring, nor does due process demand, a hearing when it appears conclusively from the applicant's "pleadings" that it cannot succeed.[17]

The NAS–NRS panels evaluated approximately 16,500 claims made on behalf of the 4,000 drugs marketed pursuant to effective NDAs in 1962. Seventy percent of these claims were found not to be supported by substantial evidence of effectiveness, and only 434 drugs were found effective for all their claimed uses. If the FDA were required automatically to hold a hearing for each product whose efficacy was questioned by the NAS–NRC

---

[17] This applies, of course, only to those regulations that are precise. For example, the plan or protocol for a study must include "a summary of the methods of analysis, and an evaluation of data derived from the study, including any appropriate statistical methods." 21 CFR § 130.12(a)(5)(ii)(*a*)(5). A mere reading of the study submitted will indicate whether the study is totally deficient in this regard. Some of the regulations, however, are not precise, as they call for the exercise of discretion or subjective judgment in determining whether a study is adequate and well-controlled. For example, § 130.12 (a)(5)(ii)(*a*)(2)(*i*) requires that the plan or protocol for the study include a method of selection of the subjects that "provide *adequate* assurance that they are suitable for the purposes of the study." (Emphasis added.) The qualitative standards "adequate" and "suitable" do not lend themselves to clear-cut definition, and it may not be possible to tell from the face of a study whether the standards have been met. Thus, it might not be proper to deny a hearing of the grounds that the study did not comply with this regulation.

study, even though many hearings would be an exericse in futility, we have no doubt that it could not fulfill its statutory mandate to remove from the market all those drugs which do not meet the effectiveness requirements of the Act.

If this were a case involving trial by jury as provided in the Seventh Amendment, there would be sharper limitations on the use of summary judgment,[18] as our decisions reveal. See, *e. g., Adickes* v. *Kress & Co.*, 398 U. S. 144, 153–161; *White Motor Co.* v. *United States*, 372 U. S. 253. But Congress surely has great leeway in setting standards for releasing on the public, drugs which may well be miracles or, on the other hand, merely easy money-making schemes through use of fraudulent articles labelled in mysterious scientific dress. The standard of "well-controlled investigations" particularized by the Regulations is a protective measure designed to ferret out those drugs for which there is no affirmative, reliable evidence of effectiveness. The drug manufacturers have full and precise notice of the evidence they must present to sustain their NDAs, and under these circumstances we find the FDA hearing regulations unexceptionable on any statutory or constitutional ground.

Our conclusion that the summary judgment procedure of the FDA is valid does not end the matter, for Hynson argues that its submission to the FDA satisfied its threshold burden. In reviewing an order of the Commissioner denying a hearing, a court of appeals must determine whether the Commissioner's findings accurately reflect the study in question and if they do, whether the deficiencies he finds conclusively render the study inadequate

---

[18] Under the Rules of Civil Procedure the party moving for summary judgment has the burden of showing the absence of a genuine issue as to any material fact. *Adickes* v. *Kress & Co.*, 398 U. S. 144, 157.

or uncontrolled in light of the pertinent regulations.[19] There is a contrariety of opinion within the Court concerning the adequacy of Hynson's submission. Since a majority are of the view that the submission was sufficient to warrant a hearing, we affirm the Court of Appeals on that phase of the case.

## II

No. 414 is a cross-petition by Hynson from the judgment of the Court of Appeals. This cross-petition raises questions concerning the "new drug" provisions of the 1962 amendments. The Court of Appeals suggested that only a district court has authority to determine whether Lutrexin is a "new drug." The Government contends that the Commissioner has authority to determine new drug status in proceedings to withdraw approval of the product's new drug application (NDA) under § 505 (e). Although Hynson agrees, some of the manufacturers, parties to other suits in this group of cases, advance the contrary view.

Prior to 1938 there was no machinery for the premarketing approval of drugs sold in commerce. Under the 1906 Act, 34 Stat. 758, adulterated and misbranded drugs were narrowly defined, and the Act provided only criminal sanctions and seizure by libel for condemnation. As previously noted, the 1938 Act provided for regulatory clearance of drugs prior to marketing and for administrative suspension of any clearance if required in interests

---

[19] Under the Administrative Procedure Act, a court reviews agency findings to determine whether they are supported by substantial evidence only in a case subject to the hearing provisions of 5 U. S. C. §§ 556 and 557 or "otherwise reviewed on the record of an agency hearing provided by statute . . . ." This is not such a case. The question with which we are concerned involves the initial agency determination whether a hearing is required by statute. See *Pfizer, Inc.* v. *Richardson*, 434 F. 2d 536, 546–547 (CA2).

of public safety. To introduce a new drug an application had to be effective with respect to that drug. The application was to become effective within a fixed period unless the agency after notice and opportunity for hearing refused to permit it to become effective, finding that it could not determine from existing evidence or had not been shown that it was safe. 52 Stat. 1041–1042, 1052. Any NDA could be suspended if clinical experience or new testing showed that the drug was not safe. *Id.*, 1053. Orders denying or suspending an NDA were reviewable on the administrative record in a district court. *Ibid.* Marketing a new drug without an effective NDA could be enjoined or made the basis of a criminal prosecution, or the drug could be seized in libel and condemnation proceedings.

There was a steady stream of NDAs under that Act supported by voluminous data.[20] Many new drugs claiming "me-too" status were marketed illegally or were launched with an advisory opinion of FDA that they were recognized as safe. It is estimated that by 1969 there were five identical or similar drugs for every drug with an effective NDA. Enormous administrative problems were created. Each NDA contained about 30 volumes, a stack 10 to 12 feet high; and some contained as many as 400 volumes of data.

It is clear to us that the FDA has power to determine whether particular drugs require an approved NDA in order to be sold to the public. The FDA is indeed the administrative agency selected by Congress to administer the Act, and it cannot administer the Act intelligently and rationally unless it has authority to determine what drugs are "new drugs" under § 201 (p) and whether they

[20] 1939 Annual Report, FDA; 1941 Annual Report FDA; Annual Reports, Federal Security Agency (1938–1952); Annual Reports HEW (1953–1962).

are exempt from the efficacy requirements of the 1962 amendments by the grandfather clause of § 107 (c)(4).

Regulatory agencies have by the requirements of particular statutes usually proceeded on a case-by-case basis, giving each person subject to regulation separate hearings. But there is not always a constitutional reason why that must be done. *United States* v. *Storer Broadcasting Co.,* 351 U. S. 192, is one example. We there upheld rules of the Federal Communications Commission limiting the number of broadcasting stations a single individual might own, saying that that was a proper exercise of the agency's "rule-making authority necessary for the orderly conduct of its business." *Id.,* at 202. The comprehensive rather than the individual treatment may indeed be necessary for quick effective relief. See *Permian Basin Area Rate Cases,* 390 U. S. 747. A generic drug—which is found to be unsafe and/or lacking in efficacy—may be manufactured by several persons or manufacturers. To require separate judicial proceedings to be brought against each, as if each were the owner of a Black Acre being condemned, would be to create delay where in the interests of public health there should be prompt action. A single administrative proceeding in which each manufacturer may be heard is constitutionally permissible measured by the requirements of procedural due process.

FDA maintains that a withdrawal of any NDA approval covers all "me-too" drugs. For the reasons stated that procedure is a permissible one where every manufacturer of a challenged drug has an opportunity to be heard. FDA under § 5 (e) of the Administrative Procedure Act, 5 U. S. C. § 544 (e), may issue a declaratory order governing all drugs covered by a particular NDA. That section prescribes the procedures an agency must follow "in every case of adjudication required by statutes

to be determined on the record after opportunity for an agency hearing." The industry maintains that § 5 (e) is of no avail to FDA because in a withdrawal proceeding a common issue is whether a drug is a "new drug." That issue, it is argued, can be resolved only in a court proceeding where there is an adjudication "on the record of a hearing." But that assumes an individualized hearing and adjudication as is common in regulatory proceedings. Section 5 (e), however, does not place administrative proceedings in that straitjacket. It provides that an agency "in its sound discretion, may issue a declaratory order to terminate a controversy or remove uncertainty." The termination of a controversy over a "new drug" may often be of prime importance. This is an age of ever-expanding dockets at the administrative as well as at the judicial level. If the administrative controls over drugs are to be efficient, they must be exercised with dispatch. Only paralysis would result if case-by-case battles in the courts were the only way to protect the public against unsafe or ineffective drugs. Moreover, if every "me-too" drug in a particular generic category had to be put to the test in court actions, great inequities might well result. It might take months to eliminate one "me-too" drug manufactured by one company from the market. Meanwhile, competitors selling drugs in the same category would go scot-free until the tedious and laborious procedures of litigation reached them. We cannot believe that Congress engaged in such an exercise in futility when it enacted the 1962 amendments. That would in effect restore the enforcement provisions to the status they enjoyed under the rather primitive 1906 Act. We hold that FDA by reasons of § 5 (e) of the Administrative Procedure Act may issue a declaratory order to terminate a controversy over a "new drug" or to remove any uncertainty whether a par-

ticular drug is a "new drug" within the meaning of § 201 (p)(1) of the Act. See *Abbott Laboratories* v. *Gardner*, 387 U. S. 136.

It is argued, however, that the only lawful purpose of an FDA hearing is to allow it a method for determining which lawsuits it will file in the future. Yet that is only another version of the tactics of delay and procrastination which the industry offers as the way best to serve industry's needs. The public needs are, however, opposed and paramount. We do not accept the invitation to hold that FDA has no jurisdiction to determine whether a particular drug is a "new drug" and to decide whether an NDA should be withdrawn.

Its determination that a product is a "new drug" or a "me-too" drug is, of course, reviewable. But its jurisdiction to determine whether it has jurisdiction is as essential to its effective operation as is a court's like power. Cf. *United States* v. *Shipp*, 203 U. S. 563, 573. The heart of the new procedures designed by Congress is the grant of primary jurisdiction to FDA, the expert agency it created. FDA does not have the final say, for review may be had not in a district court (except in a limited group of cases we will discuss), but in a court of appeals. FDA does not have unbridled discretion to do what it pleases. It procedures must satisfy the rudiments of fair play. Judicial relief is available only after administrative remedies have been exhausted.

It is argued that though FDA is empowered to decide the threshold question whether the drug is a "new drug," that power is only an incident to its power to approve or withdraw approval of NDAs. Some manufacturers, however, have no NDAs in effect and are not seeking approval of any drugs. Nevertheless, FDA may make a declaratory order that a drug is a "new drug." While that order is not reviewable in the Court of Appeals under § 505 (h), it is reviewable by the District Court

under the Administrative Procedure Act. 5 U. S. C. §§ 701–704; *Citizens to Preserve Overton Park* v. *Volpe*, 401 U. S. 402, 410; *Abbott Laboratories* v. *Gardner*, *supra*, at 139–148. By analogy an agency order declaring a commodity not exempt from regulation is normally a declaratory order that is reviewable, as we held in *Frozen Food Express* v. *United States*, 351 U. S. 40.

The question then presented is whether FDA properly exercised its jurisdiction in this case. As indicated above, Hynson in requesting an administrative hearing also asked FDA to decide that Lutrexin is not a "new drug" within the meaning of § 201 (p) as amended, 21 U. S. C. § 321 (p).[21] In addition, it asked that Lutrexin be "grandfathered" under § 107 (c)(4) of the 1962 amendments.[22] The Commissioner rejected both claims.

---

[21] That section provides:

"The term 'new drug' means—

"(1) Any drug (except a new animal drug or an animal feed bearing or containing a new animal drug) the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof, except that such a drug not so recognized shall not be deemed to be a 'new drug' if at any time prior to the enactment of this Act it was subject to the Food and Drugs Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use; or

"(2) Any drug (except a new animal drug or an animal feed bearing or containing a new animal drug) the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions."

[22] That section provides:

"In the case of any drug which, on the first day immediately preceding the enactment date, (A) was commercially used or sold in the United States, (B) was not a new drug as defined by section

Finding that Hynson had failed to present any evidence of adequate and well-controlled investigations in support of Lutrexin's effectiveness, he concluded that "there is no data base upon which experts can fairly and responsibly conclude that the safety and effectiveness of the drugs has been proven and is so well established that the drugs can be generally recognized among such experts as safe and effective for their intended uses." The Commissioner also held that Lutrexin is not exempt under § 107 (c)(4) because its NDA, which had become effective in 1953, had not been withdrawn prior to the enactment of the 1962 amendments and thus was "covered by an effective application" within the meaning of § 107 (c)(4)(C). The Court of Appeals affirmed the Commissioner's ruling that Lutrexin is not exempt under § 107 (c)(4). It did not discuss his holding that Lutrexin currently is a "new drug." Although we agree that the Commissioner properly ruled that Lutrexin does not come within § 107 (c)(4), we conclude that the Commissioner's order with respect to Lutrexin's "new drug" status must be vacated.

The thrust of § 201 (p) is both qualitative and quantitative. The Act, however, nowhere defines what constitutes "general recognition" among experts. Hynson contends that the "lack of substantial evidence" is applicable only to proof of the *actual* effectiveness of drugs that fall within the definition of a new drug and not to the initial determination under § 201 (p) whether a drug is "generally recognized" as effective. It would rely solely on the testimony of physicians and the extant

201 (p) of the basic Act as then in force, and (C) was not covered by an effective application under section 505 of that Act, the amendments to section 201 (p) made by this Act shall not apply to such drug when intended solely for use under conditions prescribed, recommended, or suggested in labeling with respect to such drug on that day."

literature, evidence that has been characterized as "anecdotal." We agree with FDA, however, that the statutory scheme and overriding purpose of the 1962 amendments compel the conclusion that the hurdle of "general recognition" of effectiveness requires at least "substantial evidence" of effectiveness for approval of an NDA. In the absence of any evidence of adequate and well-controlled investigation supporting the efficacy of Lutrexin, *a fortiori* Lutrexin would be a "new drug" subject to the provisions of the Act.[23]

As noted, the 1962 amendments for the first time gave FDA power to scrutinize and evaluate drugs for effectiveness as well as safety. The Act requires FDA to disapprove any application when there is a lack of "substantial evidence" that the applicant's drug is effective. § 505 (d), 21 U. S. C. § 355 (d). Similarly, he may withdraw approval for any drug if he subsequently determines that there is a lack of such evidence. § 505 (e), 21 U. S. C. § 355 (e). Evidence may be accepted only if it consists of "adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved . . . . § 505 (d), 21 U. S. C. § 355 (d). The legislative history of the Act indicates that the test was to be a rigorous one. The "substantial evidence" requirement reflects the conclusion of Congress, based upon hearings,[24] that clinical impressions of practicing physicians and poorly controlled experiments do not constitute an adequate basis for establishing efficacy. This policy underlies the regulations defining the contours of "substantial evidence": "Uncontrolled studies

---

[23] It also follows that if Hynson were not entitled to a hearing under § 505 (e), it would not be entitled to a hearing on its claim that Lutrexin is not a "new drug."

[24] See Hearings, *supra*, n. 14.

or partially controlled studies are not acceptable as the sole basis for the approval of claims of effectiveness. Such studies, carefully conducted and documented, may provide corroborative support of well-controlled studies . . . . Isolated case reports, random experience, and reports lacking the details which permit scientific evaluation will not be considered." 21 CFR § 130.12 (a)(5)(ii)(*c*).

These efficacy requirements were not designed to be prospective only. Clearly, after the initial two-year moratorium on existing drugs, FDA has the power to withdraw an application which became effective prior to the adoption of the 1962 amendments, if the applicant has not provided "substantial evidence" of the drug's efficacy. The Act plainly contemplates that such drugs will be evaluated on the basis of adequate and well-controlled investigations. Hynson would have us hold that withdrawal proceedings can be thwarted by a showing of general recognition of effectiveness based merely on expert testimony and reports with respect to investigations and clinical observation regardless of the controls used. But, we cannot construe § 201 (p) to deprive FDA of jurisdiction over a drug which, if subject to FDA regulation, could not be marketed because it had not passed the "substantial evidence" test. To do so "would be to impute to Congress a purpose to paralyze with one hand what it sought to promote with the other." *Clark* v. *Uebersee Finanz-Korp.*, 332 U. S. 480, 489.

Moreover, the interpretation of § 201 (p) urged by Hynson is not consistent with the statutory scheme as it operates on a purely prospective basis. Under subsection (2), a drug cannot transcend "new drug" status until it has been used "to a material extent or for a material time." Yet, a drug cannot be marketed lawfully before an NDA has been approved by the Commissioner on the

basis of "substantial evidence." As the Solicitor General argues, "the Act is designed so that drugs on the market, unless exempt, will have mustered the requisite scientifically reliable evidence of effectivness long before they are in a position to drop out of active regulation by ceasing to be a 'new drug.'"

It is well established that our task in interpreting separate provisions of a single Act is to give the Act "the most harmonious, comprehensive meaning possible" in light of the legislative policy and purpose. *Id.*, at 488; see *United States* v. *An Article of Drug . . . Bacto-Unidisk*, 394 U. S. 784, 798. We accordingly have concluded that a drug can be "generally recognized" by experts as effective for intended use within the meaning of the Act only when that expert consensus is founded upon "substantial evidence" as defined in § 505 (d). We have held in No. 394, however, that the Commissioner was not justified in withdrawing Hynson's NDA without a prior hearing on whether Hynson had submitted "substantial evidence" of Lutrexin's effectiveness. Consequently, any ruling as to Lutrexin's "new drug" status is premature and must await the outcome of this hearing.

Finally, we cannot agree with Hynson that Lutrexin is exempt from the provisions of the Act by virtue of § 107 (c)(4) of the 1962 amendments. That section provides that no drug will be treated as a "new drug" if, on the day preceding the adoption of the amendments, the drug "(A) was commercially used or sold in the United States, (B) was not a new drug as defined by section 201 (p) of the basic Act as then in force, and (C) was not covered by an effective application under section 505 of that Act . . . ." The applicability of this section turns solely on whether Lutrexin was "covered" by an effective NDA immediately prior to the adoption of the 1962 amendments. Hynson argues that when Lutrexin became gen-

erally recognized as safe and was no longer a "new drug," its NDA ceased to be effective.[25]

That argument draws no statutory support. The 1938 Act did not provide any mechanism, other than the Commissioner's suspension authority under § 505 (e), whereby an NDA once effective could cease to be effective. Indeed, § 505 (e) leads to the conclusion that an NDA remains effective unless it is suspended. That section empowers FDA to withdraw approval of an NDA whenever new evidence comes to light suggesting that the drug has become unsafe, whether or not the drug was generally recognized as safe in the interim.

Moreover, Hynson's argument, as the Court of Ap-

---

[25] Hynson also argues that Lutrexin is exempt by operation of § 107 (c)(2), which provides:

"An application filed pursuant to section 505 (b) of the basic Act which was 'effective' within the meaning of that Act on the day immediately preceding the enactment date shall be deemed, as of the enactment date, to be an application 'approved' by the Secretary within the meaning of the basic Act as amended by this Act."

Hynson contends that Lutrexin, generally recognized as safe prior to 1962, was not a "new drug" under applicable standards before the 1962 amendments. Thus, the argument goes, its NDA had ceased to be effective and could not be deemed "approved" under § 107 (c)(2). Consequently, there was no approval that could be withdrawn in administrative proceedings pursuant to § 505 (e).

This argument shares a common thread with the argument under § 107 (c)(4)—that the NDA for Lutrexin had ceased to be effective. The argument is no more persuasive under § 107 (c)(2) than § 107 (c)(4). In addition, the construction offered by Hynson would upset the carefully drawn transitionary provisions of §§ 107 (c)(2) and (c)(3). Since the Commissioner now must affirmatively approve or disapprove all NDAs, § 107 (c)(2) was enacted to remove the administrative burden of approving each and every NDA then effective. It also protected the market authority of all manufacturers that had effective NDAs. Without this provision, no manufacturer whose drug had become generally recognized as safe could have continued to market the drug if it was not also generally recognized as effective.

peals recognized, would render clause (C) superfluous. Under Hynson's reasoning, any drug that could satisfy clause (B)—*i. e.*, any drug that had become generally recognized as safe—automatically would satisfy clause (C). This construction, therefore, offends the well-settled rule of statutory construction that all parts of a statute, if at all possible, are to be given effect. See, *e. g.*, *Jarecki* v. *G. D. Searle & Co.*, 367 U. S. 303, 307; *Ginsberg & Sons* v. *Popkin*, 285 U. S. 204, 208. The interpretation accorded by the Commissioner and the Court of Appeals, on the other hand, does give clause (C) operative effect. It would limit the exemption to drugs, generally recognized as safe, which had not come under the blanket of an effective NDA. This interpretation accords with the legislative history which suggests that the exemption is afforded only for drugs that never had been subject to new drug regulation.[26]

Except with the modification with respect to Lutrexin's "new drug" status, the judgment of the Court of Appeals is

*Affirmed.*

MR. JUSTICE BRENNAN took no part in the consideration or decision of these cases. MR. JUSTICE STEWART took no part in the decision of these cases.

---

[26] See S. Rep. No. 1744, 87th Cong., 2d Sess., pt. 2, at 8; H. R. Rep. No. 2464, 87th Cong., 2d Sess., 12; H. R. Rep. No. 2526, 87th Cong., 2d Sess., 22–23. Hynson contends that the construction afforded by FDA renders the exemption nugatory and defeats the legislative purpose. The provision, however, does exempt drugs that, as a generic class, were never subject to new drug regulation. These consist primarily of over-the-counter drugs which, although they were not "grandfathered" under the 1938 Act, were not subject to new drug regulation because of universal recognition of the safety of their old, established ingredients at the time they came on the market.

21 CFR § 130.12 (a)(5)(ii) provides:

(ii) The following principles have been developed over a period of years and are recognized by the scientific community as the essentials of adequate and well-controlled clinical investigations. They provide the basis for the determination whether there is "substantial evidence" to support the claims of effectiveness for "new drugs" and antibiotic drugs.

(*a*) The plan or protocol for the study and the report of the results of the effectiveness study must include the following:

(1) A clear statement of the objectives of the study.

(2) A method of selection of the subjects that—

(*i*) Provides adequate assurance that they are suitable for the purposes of the study, diagnostic criteria of the condition to be treated or diagnosed, confirmatory laboratory tests where appropriate, and, in the case of prophylactic agents, evidence of susceptibility and exposure to the condition against which prophylaxis is desired.

(*ii*) Assigns the subjects to test groups in such a way as to minimize bias.

(*iii*) Assures comparability in test and control groups of pertinent variables, such as age, sex, severity, or duration of disease, and use of drugs other than the test drug.

(3) Explains the methods of observation and recording of results, including the variables measured, quantitation, assessment of any subjective response, and steps taken to minimize bias on the part of the subject and observer.

(4) Provides a comparison of the results of treatment or diagnosis with a control in such a fashion as to permit quantitative evaluation. The precise nature of the control must be stated and an explanation given of the methods used to minimize bias on the part of the observers and the analysts of the data. Level and methods of "blinding," if used, are to be documented. Generally, four types of comparison are recognized:

(*i*) No treatment: Where objective measurements of effectiveness are available and placebo effect is negligible, comparison of the objective results in comparable groups of treated and untreated patients.

(*ii*) Placebo control: Comparison of the results of use of the new drug entity with an inactive preparation designed to resemble the test drug as far as possible.

(*iii*) Active treatment control: An effective regimen of therapy may be used for comparison, e. g., where the condition treated is such that no treatment or administration of a placebo would be contrary to the interest of the patient.

(*iv*) Historical control: In certain circumstances, such as those involving diseases with high and predictable mortality (acute leukemia of childhood), with signs and symptoms of predictable duration or severity (fever in certain infections), or, in case of prophylaxis, where morbidity is predictable, the results of use of a new drug entity may be compared quantitatively with prior experience historically derived from the adequately documented natural history of the disease or condition in comparable patients or populations with no treatment or with a regimen (therapeutic, diagnostic, prophylactic) the effectiveness of which is established.

(5) A summary of the methods of analysis, and an evaluation of data derived from the study, including any appropriate statistical methods.

*Provided, however,* That any of the above criteria may be waived in whole or in part, either prior to the investigation or in the evaluation of a completed study, by the Director of the Bureau of Drugs with respect to a specific clinical investigation; a petition for such a waiver may be filed by any person who would be adversely affected by the application of the criteria to a particular clinical investigation; the petition should show that some or all of the criteria are not reasonably applicable to the investigation and that alternative procedures can be, or have been, followed, the results of which will or have yielded data that can and should be accepted as substantial evidence of the drug's effectiveness. A petition for a waiver shall set forth clearly and concisely the specific provision or provisions in the criteria from which waiver is sought, why the criteria are not reasonably applicable to the particular clinical investigation, what alternative procedures, if any, are to be, or have been, employed, what results have been obtained, and the basis on which it can be, or has been, concluded that the clinical investigation will or has yielded substantial evidence of effectiveness, notwithstanding nonconformance with the criteria for which waiver is requested.

(*b*) For such an investigation to be considered adequate for approval of a new drug, it is required that the test drug be standardized as to identity, strength, quality, purity, and dosage form to give significance to the results of the investigation.

(*c*) Uncontrolled studies or partially controlled studies are not acceptable as the sole basis for the approval of claims of effectiveness. Such studies, carefully conducted and documented, may provide

corroborative support of well-controlled studies regarding efficacy and may yield valuable data regarding safety of the test drug. Such studies will be considered on their merits in the light of the principles listed here, with the exception of the requirement for the comparison of the treated subjects with controls. Isolated case reports, random experience, and reports lacking the details which permit scientific evaluation will not be considered.

# SUPREME COURT OF THE UNITED STATES

Nos. 72–394 AND 72–414

| | |
|---|---|
| Casper W. Weinberger, Secretary of Health, Education, and Welfare, et al., Petitioners, 72–394 *v.* Hynson, Westcott and Dunning, Incorporated. | On Writs of Certiorari to the United States Court of Appeals for the Fourth Circuit. |
| Hynson, Westcott and Dunning, Incorporated, Petitioner, 72–414 *v.* Casper W. Weinberger, Secretary of Health, Education, and Welfare, et al. | |

[June 18, 1973]

MR. JUSTICE POWELL, concurring in part, and concurring in the result in part.

I concur in Part II of the Court's opinion, which disposes of the issues raised by Hynson, Westcott and Dunning, Incorporated, in its cross-petition (No. 72–414). As to Part I, which addresses issues raised in the petition filed by the Commissioner of FDA (No. 72–394), I concur only in the result and state briefly the limited sense in which I accept the Court's conclusion.

Insofar as the Court today sustains the holding below that Hynson's submission to FDA raised "a genuine and substantial issue of fact" requiring a hearing on the ultimate issue of efficacy, 21 CFR § 130.14 (b) (1970), I am in accord. Hynson's presentation in support of the efficacy of Lutrexin clearly justified a hearing as to whether the drug was supported by "adequate and well

controlled investigations," 21 U. S. C. § 355 (d), even as that term is defined in the Commission's regulations. 21 CFR § 130.12 (a)(5) (1970). For this reason I concur in the result reached in this case. I cannot agree on this record, however, with any implications or conclusions in the Court's opinion to the effect that the regulations—as construed and applied by the Commissioner in this case—are either compatible with the statutory scheme or constitutional under the Due Process Clause.[1] Such questions have not been squarely presented in this case and, in light of the Court's conclusion that Hynson has complied with the regulations, their resolution is unnecessary to the Court's decision.

Were we required to reach these issues, there may well be serious doubt whether the Commissioner's rigorous threshold specifications as to proof of "adequate and well controlled investigations," coupled with his restrictive summary judgment regulation, go beyond the statutory requirements and in effect frustrate the congressional mandate for a prewithdrawal "opportunity for hearing." 21 U. S. C. § 355 (e). There is also a genuine issue of procedural due process where, as in this case, the Commissioner construes his regulations to deny a hearing as to the efficacy of a drug established and used by the medical profession for two decades, and where its effectiveness is supported by a significant volume of clinical data and the informed opinions of experts whose qualifications are not questioned.[2]

---

[1] Cf. *Fuentes* v. *Shevin*, 407 U. S. 67, 80 (1970), and cases cited therein. I do not question. of course, the authority of the Commissioner to adopt reasonable regulations consistent with the statute and which do not, as applied, deprive persons of their property without the elementary due process of a fair opportunity for a hearing.

[2] There can be no doubt, both from the legislative history and the language of the 1962 amendments to the Act, that Congress intended

These important and complex questions should await decision in future cases in which the issues are briefed fully and are necessary to the Court's decision.

---

to impose standards that would bar reliance upon anecdotal evidence or mere professions of belief by doctors as determinative of a drug's efficacy. But it is also clear that Congress intended to protect against the arbitrary withdrawal or withholding of approval of a drug where there is "substantial evidence" of its effectiveness. To provide protection against such action, especially when authority is vested in an official who acts in an administrative as well as judicial capacity, the Act specifically provides for a hearing. The public interest is twofold: (i) to remove from the market, in accordance with due process, drugs of no utility or effectiveness; and (ii) to retain on the market those drugs that are efficacious. In an understandable zeal to remove the former, an administrative agency must not overlook both the interest of the public and the right of the proprietor in protecting the drugs that are useful in the prevention, control or treatment of illness.

# SUPREME COURT OF THE UNITED STATES

Syllabus

## CIBA CORP. *v.* WEINBERGER ET AL.

CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

No. 72-528. Argued April 17, 1973—Decided June 18, 1973

Petitioner manufactures a drug called Ritonic Capsules, for which it filed a new drug application (NDA) that became effective in 1959, on the basis of the drug's safety. After the enactment of the 1962 amendments to the Federal Food, Drug, and Cosmetic Act, the Food and Drug Administration (FDA) withdrew approval of the NDA on the ground that there was no substantial evidence that the drug was *effective* as claimed, under § 505 of the Act. Petitioner sought review of the withdrawal order in the Court of Appeals for the Second Circuit, as provided in § 505 (h), and that court affirmed the order. Prior to the issuance of the withdrawal order petitioner sought declaratory and injunctive relief in the New Jersey District Court, which granted the Government's motion to dismiss the complaint for lack of jurisdiction. The Court of Appeals for the Third Circuit affirmed, holding that the FDA was authorized to decide the jurisdictional question as an incident of its power to approve or withdraw approval for NDA's, that its decision was reviewable on direct appeal by a court of appeals, and since the Court of Appeals for the Second Circuit had ruled against petitioner on that appeal, the jurisdictional issue could not be relitigated in a separate suit for a declaratory judgment. *Held:*

1. The FDA has jurisdiction in an administrative proceeding to determine whether a drug product is a "new drug" within the meaning of § 201 (p) of the Act. *Weinberger* v. *Bentex Pharmaceuticals, Inc., post*, p. —. P. 3.

2. While the Act provides FDA with sanctions, such as civil injunction proceedings, criminal penalties, *in rem* seizure and condemnation, to enforce the prohibition against sale in commerce of any article in violation of § 505, the Act does not create a dual system, one administrative and the other judicial. P. 3.

Syllabus

3. Where petitioner had an opportunity to litigate the "new drug" issue before the FDA and to raise the issue on appeal to a court of appeals, it may not relitigate the issue in another proceeding. P. 4.

463 F. 2d 225, affirmed.

DOUGLAS, J., delivered the opinion of the Court, in which all Members joined, except BRENNAN, J., who took no part in the consideration or decision of the case, and STEWART, J., who took no part in the decision of the case.

NOTICE: This opinion is subject to formal revision before publication in the preliminary print of the United States Reports. Readers are requested to notify the Reporter of Decisions, Supreme Court of the United States, Washington, D.C. 20543, of any typographical or other formal errors, in order that corrections may be made before the preliminary print goes to press.

# SUPREME COURT OF THE UNITED STATES

No. 72-528

| | |
|---|---|
| CIBA Corporation, Petitioner, *v.* Caspar W. Weinberger, Secretary of Health, Education, and Welfare, et al. | On Writ of Certiorari to the United States Court of Appeals for the Third Circuit. |

[June 18, 1973]

MR. JUSTICE DOUGLAS delivered the opinion of the Court.

Petitioner manufactures a drug called Ritonic Capsules* for which it filed an NDA that became effective in 1959. Under the Act then in force an NDA for a "new drug" required the manufacturer to submit to FDA adequate proof of the drug's safety. This particular NDA became effective on the basis of the drug's safety. As we have noted in the companion cases the 1962 amendments to the Federal Food, Drug and Cosmetic Act of 1938 directed FDA to withdraw approval for NDAs which became effective prior to that time if after notice and opportunity for hearing, it is found that there is a lack of "substantial evidence" that the drug involved is *effective* as claimed in its labeling. And as we have noted, "substantial evidence" as used in the Act, § 505 (d) and § 505 (e)(3), means "adequate and well-controlled in-

*It is a prescription drug recommended "for patients who are losing their drive, alertness, vitality and zest for living because of the natural degenerative changes of advancing years"; and for patients who are "debilitated or depressed by chronic illness, overwork, etc., as well as those recuperating from illness or surgery."

vestigations" from which experts may conclude that the drug will have the claimed effect.

A panel of NAS–NRC reviewed the claims made for ritonic capsules and found it "ineffective" for each of the claims. FDA concluded there was a lack of substantial evidence of their efficacy and gave notice of its intent to withdraw the NDA, offering petitioner an opportunity to submit the required kind of data bearing on the efficacy of the drug and stating that withdrawal of approval of the NDA would cause the ritonic capsules to be a "new drug" for which no NDA was in effect, thereby making future sales unlawful.

Petitioner responded, submitting data on the issue of efficacy and maintained that ritonic capsules was not a "new drug" for purposes of the Act as amended. FDA concluded that petitioner's evidence was insufficient to establish effectiveness and gave notice of a hearing on the withdrawal of the NDA. Petitioner responded, contested FDA's authority to proceed further, and claimed that the product was not a "new drug" under the 1952 Act. It reserved the right to establish its position in the administrative proceedings, in judicial proceedings, or in both. Petitioner filed no more data to support its position; and accordingly FDA withdrew approval of the NDA on the ground that there was no substantial evidence that the drug was effective as claimed. Petitioner sought review of the withdrawal order in the Court of Appeals for the Second Circuit, as provided in § 505 (h). The Court of Appeals affirmed the withdrawal order. *Ciba-Geigy Corp.* v. *Richardson*, 446 F. 2d 466.

Meanwhile, and prior to the issuance of the withdrawal order, petitioner brought suit in the New Jersey District Court seeking declaratory and injunctive relief. After hearing the District Court granted the Govern-

ment's motion to dismiss the complaint for lack of jurisdiction. On appeal the Third Circuit Court of Appeals affirmed, 463 F. 2d 225, holding that FDA was authorized to decide the jurisdictional question as an incident of its power to approve or withdraw approval for NDAs, that its decision on that issue was reviewable on direct appeal by a court of appeals, and since the Second Circuit Court of Appeals had ruled against petitioner on that appeal, the jurisdictional question could not be relitigated in a separate suit for a declaratory judgment. We affirm the Court of Appeals.

We have stated in the *Bentex* case our reasons for concluding that FDA has jurisdiction in an administrative proceeding to determine whether a drug product is a "new drug" within the meaning of § 201 (p) of the Act. A decision that FDA lacks authority to determine in its own proceedings the coverage of the Act it administers, subject of course to judicial review, would seriously impair FDA's ability to discharge the responsibilities placed on it by Congress. As we said in the *Hynson* cases and the *Bentex* case, *ante,* the definition of "new drug" as used in § 3201 (p)(1) involves a determination of technical and scientific questions by experts. The agency is therefore appropriately the arm of Government to make the threshold determination of the issue of coverage. Cf. *Oklahoma Press Publishing Co.* v. *Walling,* 327 U. S. 186, 210–211, n. 47.

It is of course true that the Act gives FDA a second line of defense—civil injunction proceedings, criminal penalties, and *in rem* seizure and condemnation. See §§ 302 (a), 303, 304. Those are sanctions to enforce the prohibition of the Act against the sale in commerce of any article in violation of § 505. But the Act does not create a dual system of control—one administrative, and the other judicial. Cases may arise where there has been no formal administrative determination of the "new

drug" issue, it being first tendered to a district court. Even then, however, the District Court might well stay its hand, awaiting an appropriate administrative determination of the threshold question. See the *Bentex* case, *ante*. Where there is, however, an administrative determination, whether it be explicit or implicit in the withdrawal of an NDA, the tactic of "reserving" the threshold question (the jurisdictional issue) for later judicial determination is not tolerable. There is judicial review of FDA's ruling. But petitioner, having an opportunity to litigate the "new drug" issue before FDA and to raise the issue on appeal to a court of appeals, may not relitigate the issue in another proceeding. *Yakus* v. *United States*, 321 U. S. 414, 444–446.

*Affirmed.*

MR. JUSTICE BRENNAN took no part in the consideration or decision of this case. MR. JUSTICE STEWART took no part in the decision of this case.

NOTE: Where it is feasible, a syllabus (headnote) will be released, as is being done in connection with this case, at the time the opinion is issued. The syllabus constitutes no part of the opinion of the Court but has been prepared by the Reporter of Decisions for the convenience of the reader. See *United States* v. *Detroit Lumber Co.*, 200 U.S. 321, 337.

# SUPREME COURT OF THE UNITED STATES

## Syllabus

## UNITED STATES ET AL. *v.* STUDENTS CHALLENGING REGULATORY AGENCY PROCEDURES (SCRAP) ET AL.

APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

No. 72-535. Argued February 28, 1973—Decided June 18, 1973*

The Interstate Commerce Act permits railroads to file proposed freight rate increases, with at least 30 days' notice to the Interstate Commerce Commission (ICC) and the public before putting the new rates into effect. The ICC may, pursuant to § 15 (7) of the Act, suspend the operation of the proposed rates for as long as seven months, in order to investigate the lawfulness of the rates. At the end of the seven-month period, the carrier may put the suspended rates into effect unless the ICC has completed its investigation and found the rates unlawful. Proceeding under the statutory scheme, substantially all the Nation's railroads sought a 2.5% surcharge on nearly all freight rates, as an emergency measure to obtain increased revenues pending adoption of selective rate increases on a permanent basis. Shippers, competing carriers, and other interested persons requested the ICC to suspend the tariff for the statutory seven-month period. Various environmental groups, including Students Challenging Regulatory Agency Procedures (SCRAP) and the Environmental Defense Fund (EDF), appellees here, protested that failure to suspend the surcharge would cause their members "economic, recreational and aesthetic harm," and specifically, that the new rate structure would discourage the use of "recyclable" materials and promote the use of raw materials that compete with scrap, thus adversely affecting the environment. On February 1, 1972, the ICC issued an order

---

*Together with No. 72-562, *Aberdeen & Rockfish Railroad Co. et al.* v. *Students Challenging Regulatory Agency Procedures (SCRAP) et al.*, also on appeal from the same court.

Syllabus

announcing its decision not to suspend the surcharge for the seven-month period, and on April 24, 1972, ordered the proposed selective increases filed by the carriers to be suspended for the full seven-month period ending November 30, 1972, and permitted the collection of the surcharge until that date. SCRAP filed the present suit seeking, *inter alia*, an injunction to restrain enforcement of the February 1 and April 24 orders allowing the carriers to collect the surcharge. SCRAP, an unincorporated association formed by five law students to enhance the quality of the environment, claimed that its members "suffered economic, recreational and aesthetic harm directly as a result of the adverse environmental impact of the railroad freight structure," that each of its members was caused to pay more for finished products, that each of its members uses the forests, rivers, mountains, and other natural resources of the Washington area and at his legal residence for camping, hiking, fishing, and other purposes, and that these uses have been adversely affected by increased freight rates. The main thrust of SCRAP's complaint was that the ICC's orders were unlawful for failure to include a detailed environmental impact statement as required by § 102 (C) of the National Environmental Policy Act of 1969 (NEPA), 42 U. S. C. § 4332(C). The three-judge District Court found that appellees had standing to sue. The court held that its power to grant an injunction was not barred by *Arrow Transportation Co.* v. *Southern R. Co.*, 372 U. S. 658, because NEPA "implicitly confers authority on the federal courts to enjoin *any* federal action taken in violation of NEPA's procedural requirements . . . so long as the review is confined to a determination as to whether the procedural requisites of NEPA have been followed." The court concluded that the ICC's decision not to suspend the surcharge for the seven-month period was a "major federal action significantly affecting the quality of the human environment," and granted an injunction prohibiting the ICC "from permitting" and the railroads "from collecting" the surcharge "insofar as that surcharge relates to goods being transported for purposes of recycling." *Held:*

1. Appellees' pleadings sufficiently alleged that they were "adversely affected" or "aggrieved" within the meaning of § 10 of the Administrative Procedure Act to withstand a motion to dismiss on the ground of lack of standing to sue. *Sierra Club* v. *Morton*, 405 U. S. 727, distinguished. Pp. 13–19.

(a) Standing is not confined to those who show economic harm, as "[a]esthetic and environmental well-being, like economic

well-being, are important ingredients of the quality of life in our society." *Sierra Club, supra,* at 734. P. 15.

(b) Here, the appellees claimed that the specific and allegedly illegal action of the ICC would directly harm them in their use of the natural resources of the Washington area. Pp. 15–16.

(c) Standing is not to be denied because many people suffer the same injury. Pp. 16–17.

(d) It cannot be said on these pleadings that appelles could not prove their allegations, which, if proved, would place them squarely among those persons injured in fact by the ICC's action and entitled to review under *Sierra Club, supra.* Pp. 17–19.

2. The District Court lacked jurisdiction to issue the injunction. Pp. 19–27.

(a) *Arrow Transportation, supra,* held that Congress in § 15 (7) had vested exclusive jurisdiction in the ICC to suspend rates pending its final decision on their lawfulness and had deliberately extinguished judicial power to grant such relief; and the factual distinctions between the instant case and *Arrow Transportation* are inconsequential. Pp. 19–21.

(b) The alleged noncompliance by the ICC with NEPA did not give the District Court authority to grant the injunction, as NEPA was not intended to repeal by implication any other statute, and the policies identified in *Arrow Transportation* as the basis for § 15 (7) would be substantially undermined if the courts were found to have suspension powers simply because of noncompliance with NEPA. Pp. 21–26.

346 F. Supp. 189, reversed and remanded.

STEWART, J., delivered the opinion of the Court, which BRENNAN and BLACKMUN, JJ., joined; in Parts I and II of which DOUGLAS and MARSHALL, JJ., joined; and in Parts I and III of which BURGER, C. J., and WHITE and REHNQUIST, JJ., joined. BLACKMUN, J., filed a concurring opinion, in which BRENNAN, J., joined. DOUGLAS, J., filed an opinion dissenting in part. WHITE, J., filed an opinion dissenting in part, in which BURGER, C. J., and REHNQUIST, J., joined. MARSHALL, J., filed an opinion concurring in part and dissenting in part. POWELL, J., took no part in the consideration or decision of the cases.

# SUPREME COURT OF THE UNITED STATES

Nos. 72–535 AND 72–562

United States and Interstate Commerce Commission, Appellants,
72–535 v.
Students Challenging Regulatory Agency Procedures (SCRAP) et al.

Aberdeen and Rockfish Railroad Company et al., Appellants,
72–562 v.
Students Challenging Regulatory Agency Procedures (SCRAP) et al.

On Appeals from the United States District Court for the District of Columbia.

[June 18, 1973]

MR. JUSTICE STEWART delivered the opinion of the Court.

Under the Interstate Commerce Act, the initiative for rate increases remains with the railroads. But in the absence of special permission from the Interstate Commerce Commission, a railroad seeking an increase must provide at least 30 days' notice to the Commission and the public before putting the new rate into effect. 49 U. S. C. § 6 (3).[1] During that 30-day period, the Com-

[1] 49 U. S. C. § 6 (3) provides: "No change shall be made in the rates, fares, and charges or joint rates, fares, and charges which have been filed and published by any common carrier in compliance with the requirements of this section, except after thirty days'

mission may suspend the operation of the proposed rate for a maximum of seven months pending an investigation and decision on the lawfulness of the new rates. 49 U. S. C. § 15 (7).[2] At the end of the seven-month

---

notice to the Commission and to the public published as aforesaid, which shall plainly state the changes proposed to be made in the schedule then in force and the time when the changed rates, fares, or charges will go into effect; and the proposed changes shall be shown by printing new schedules, or shall be plainly indicated upon the schedules in force at the time and kept open to public inspection: *Provided*, That the Commission may, in its discretion and for good cause shown, allow changes upon less than the notice herein specified, or modify the requirements of this section in respect to publishing, posting, and filing of tariffs, either in particular instances or by a general order applicable to special or peculiar circumstances or conditions: *Provided further*, That the Commission is authorised to make suitable rules and regulations for the simplification of schedules of rates, fares, charges, and classifications and to permit in such rules and regulations the filing of an amendment of or change in any rate, fare, charge, or classification without filing complete schedules covering rates, fares, charges or classifications not changed if, in its judgment, not inconsistent with the public interest."

[2] 49 U. S. C. § 15 (7) provides in pertinent part: "Whenever there shall be filed with the Commission any schedule stating a new . . . rate, fare, or charge, . . . the Commission shall have . . . authority, either upon complaint or upon its own initiative without complaint, at once, and if it so orders without answer or other formal pleading by the interested carrier or carriers, but upon reasonable notice, to enter upon a hearing concerning the lawfulness of such rate, fare, [or] charge . . . ; and pending such hearing and the decision thereon the Commission, upon filing with such schedule and delivering to the carrier or carriers affected thereby a statement in writing of its reasons for such suspension, may from time to time suspend the operation of such schedule and defer the use of such rate, fare, [or] charge . . . , but not for a longer period than seven months beyond the time when it would otherwise go into effect; and after full hearing, whether completed before or after the rate, fare, [or] charge . . . goes into effect, the Commission may make such order with reference

period, the carrier may put the suspended rate into effect unless the Commission has earlier completed its investigation and found the rate unlawful.[3]

Proceeding under this regulatory scheme, on December 13, 1971, substantially all of the railroads in the United States requested Commission authorization to file on 5 days' notice a 2.5% surcharge on nearly all freight rates. The railroads sought a January 1, 1972 effective date for the new rates. The surcharge was proposed as an interim emergency measure designed to produce some $246 million annually in increased revenues pending adoption of selective rate increases on a permanent basis.

As justification for the proposed surcharge, the railroads alleged increasing costs and severely inadequate

---

thereto as would be proper in a proceeding initiated after it had become effective. If the proceeding has not been concluded and an order made within the period of suspension, the proposed change of rate, fare, [or] charge . . . shall go into effect at the end of such period; but in case of a proposed increased rate or charge for or in respect to the transportation of property, the Commission may by order require the interested carrier or carriers to keep accurate account in detail of all amounts received by reason of such increase, specifying by whom and in whose behalf such amounts are paid, and upon completion of the hearing and decision may by further order require the interested carrier or carriers to refund, with interest, to the persons in whose behalf such amounts were paid, such portion of such increased rates or charges as by its decision shall be found not justified. At any hearing involving a change in a rate, fare, [or] charge . . . after September 18, 1940, the burden of proof shall be upon the carrier to show that the proposed changed rate, fare, [or] charge . . . is just and reasonable, and the Commission shall give to the hearing and decision of such questions preference over all other questions pending before it and decide the same as speedily as possible."

[3] Other statutory provisions giving suspension powers to the Commission include 49 U. S. C. §§ 316 (g), 318 (c) (Motor Carrier Act); 49 U. S. C. § 907 (g), (i) (Water Carrier Act); 49 U. S. C. § 1006 (e) (Freight Forwarders Act).

revenues. In its last general revenue increase case, less than two years earlier, the Commission had found:

> "[T]he financial condition of the railroad industry as a whole, and the financial status of many individual carriers by rail, must be found to be at a dangerously low level. The precipitous decline in working capital and serious loss of liquidity has reduced many carriers to a truly marginal operation. This has been most clearly demonstrated by the recent bankruptcy application of the Penn Central. We think it undeniable that a number of other roads are approaching a similar financial crisis." *Ex parte Nos. 265/267, Increased Freight Rates, 1970 and 1971*, 339 I. C. C. 125, 173.

The railroads alleged that, since the close of that proceeding, their costs had increased by over $1 billion on an annual basis, including $305 million in increased wages, while economic indicators such as decreased working capital and increased debt obligations pointed towards an ever worsening financial condition.[4]

In an order dated December 21, 1971, the Commission acknowledged the need, particularly of some carriers, for increased revenues, but it concluded that five days' notice and a January 1, 1972, effective date "would preclude the public from effective participation." *Ex parte No. 281, Increased Freight Rates and Charges*, 340 I. C. C. 358, 361. The Commission authorized the railroads to refile the 2.5% surcharge with not less than 30 days' notice, and an effective date no earlier than February 5, 1972.

---

[4] Figures reported to the Commission indicated that the net working capital of the Class I railroads for the 12 months ending September 30, 1971, was only $75.4 million, approximately $33.7 million less than the year-end 1970 figure. Long-term debt maturing within one year from September 30, 1971, was $43.6 million higher than on December 31, 1970. Equipment obligations at the end of 1970 were $4,448 million or almost twice the total in 1960.

On January 5, 1972, the railroads refiled the surcharge to become effective on February 5, 1972. Shippers, competing carriers, and other interested persons requested the Commission to suspend the tariff for the statutory seven-month period. Various environmnetal groups, including Students Challenging Regulatory Agency Procedures (SCRAP) and the Environmental Defense Fund (EDF), two of the appellees here, protested that failure to suspend the surcharge would cause their members "economic, recreational and aesthetic harm." Specifically, they claimed that the rate structure would discourage the use of "recyclable" materials, and promote the use of new raw materials that compete with scrap, thereby adversely affecting the environment by encouraging unwarranted mining, lumbering, and other extractive activities. The members of these environmental groups were allegedly forced to pay more for finished products, and their use of forests and streams was allegedly impaired because of unnecessary destruction of timber and extraction of raw materials, and the accumulation of otherwise recyclable solid and liquid waste materials. The railroads replied that since this was a general rate increase, recyclable materials would not be made any less competitive relative to other commodities, and that in the past general rate increases had not discouraged the movement of scrap materials.

The Commission issued an order on February 1, 1972, shortly before the surcharge would have automatically become effective. It recognized that "the railroads have a critical need for additional revenue from their interstate freight rates and charges to offset, in part, recently incurred increased operating costs," and announced its decision not to suspend the 2.5% surcharge for the seven-month statutory period.[5] In anticipation of the pro-

[5] The order of the ICC is unreported.

posed permanent selective increases to be filed by the railroads and to avoid further complication of the tariff rates, the Commission specified that its refusal to suspend was conditioned upon the carriers' setting an expiration date for the surcharge of no later than June 5, 1972.[6] The Commission ordered the investigation into the railroads' rates which had been instituted by its December 21 order to be held in abeyance until the carriers requested permission to file the indicated permanent rate increases on a selective basis. With respect to the appellees' environmental arguments, the Commission found that "the involved general increase will have no significant adverse effect on the movement of traffic by railway or on the quality of the human environment within the meaning of the [National] Environmental Policy Act of 1969."

The proposed permanent selective increases, averaging 4.1%, were subsequently filed with the Commission, and various parties again requested that these proposed rates also be suspended. By order served March 6, 1972, the Commission did not grant the railroads' request to have the selective increases go into effect on April 1, 1972, as they had requested, but it allowed the carriers to republish their rates to become effective on May 1, 1972, upon not less than 45-days notice to the public. The carriers did republish the rates, and on April 24, 1972, the Commission entered an order suspending the proposed selec-

[6] The Commission also imposed as a condition on its refusal to suspend the exclusion of increased rates "on freight in trailer bodies, semi-trailers, vehicles or containers on flat cars, on export and import traffic." Since such increases had been proposed only by the western and southern carriers and not by the eastern carriers, such increases would, in the Commission's view, have disrupted existing port relationships.

Finally, the Commission conditioned its action on the provision that the proposed surcharge would not apply to shipments originating prior to February 5, 1972, and moving under transit arrangements.

tive increase for the full seven-month period allowed by statute, or to and including November 30, 1972.[7] The investigation into the increased rates was continued. Since the selective increases were to supplant the temporary surcharge, and since they had been suspended, the Commission modified its February 1 order and authorized the railroads to eliminate the June 5 expiration date for the surcharge and to continue collecting the surcharge until November 30, 1972.

I

On May 12, 1972, SCRAP filed the present suit against the United States and the Commission in the District Court for the District of Columbia seeking, along with other relief, a preliminary injunction to restrain enforcement of the Commission's February 1 and April 24 orders allowing the railroads to collect the 2.5% surcharge.

SCRAP stated in its amended complaint that it was "an unincorporated association formed by five law students . . . in September, 1971. Its primary purpose is to enhance the quality of the human environment for its members and for all citizens . . . ." To establish standing to bring this suit, SCRAP repeated many of the allegations it had made before the Commission in *Ex parte 281*. It claimed that each of its members "suffered economic, recreational and aesthetic harm directly as a result of the adverse environmental impact of the railroad freight structure, as modified by the Commission's actions to date in *Ex Parte 281*." Specifically SCRAP alleged that each of its members was caused to pay more for finished products, that each of its members "uses the forests, rivers, streams, mountains, and other natural resources surrounding the Washington Metropolitan area and at his legal residence, for camping, hiking, fishing, sightseeing, and other recreational [and] aesthetic pur-

---

[7] The March 6 and April 24 orders of the ICC are unreported.

poses," and that these uses have been adversely affected by the increased freight rates, that each of its members breathes the air within the Washington Metropolitan Area and the area of his legal residence and that this air has suffered increased pollution caused by the modified rate structure, and that each member has been forced to pay increased taxes because of the sums which must be expended to dispose of otherwise reusable waste materials.

The main thrust of SCRAP's complaint was that the Commission's decisions of February 1 and April 24, insofar as they declined to suspend the 2.5% surcharge, were unlawful because the Commission had failed to include a detailed environmental impact statement as required by § 102 (C) of the National Environmental Policy Act of 1969 (NEPA), 42 U. S. C. § 4332 (C). NEPA requires such a statement in "every recommendation or report on proposals for legislation and other major Federal actions significantly affecting the quality of the human environment . . . ." *Ibid.*[8] SCRAP contended that because

---

[8] Section 102, 42 U. S. C. § 4332, provides in pertinent part:

"The Congress authorizes and directs that, to the fullest extent possible: (1) the policies, regulations, and public laws of the United States shall be interpreted and administered in accordance with the policies set forth in this chapter, and (2) all agencies of the Federal Government shall—

. . . . .

"(C) include in every recommendation or report on proposals for legislation and other major Federal actions significantly affecting the quality of the human environment, a detailed statement by the responsible official on—

"(i) the environmental impact of the proposed action,

"(ii) any adverse environmental effects which cannot be avoided should the proposal be implemented,

"(iii) alternatives to the proposed action.

"(iv) the relationship between local short-term uses of man's environment and the maintenance and enhancement of long-term productivity, and

"(v) any irreversible and irretrievable commitments of resources

of its alleged adverse impact upon recycling, the Commission's action with respect to the surcharge constituted a major federal action significantly affecting the environment.

Three additional environmental groups, also appellees here, were allowed to intervene as plaintiffs, and a group of railroads, appellants here, intervened as defendants to support the 2.5% surcharge.[9] After a single district

---

which would be involved in the proposed action should it be implemented.

"Prior to making any detailed statement, the responsible Federal official shall consult with and obtain the comments of any Federal agency which has jurisdiction by law or special expertise with respect to any environmental impact involved. Copies of such statement and the comments and views of the appropriate Federal, State, and local agencies, which are authorized to develop and enforce environmental standards, shall be made available to the President, the Council on Environmental Quality and to the public . . . and shall accompany the proposal through the existing agency review processes . . . ."

[9] The Environmental Defense Fund (EDF), National Parks and Conservation Association, and Izaak Walton League of America intervened as plaintiffs. The allegations as to standing made by each of these groups were similar to those made by SCRAP. EDF, for example, alleged as follows:

"EDF has a nationwide membership of over 32,000 persons composed of scientists, educators, lawyers and other citizens dedicated to the protection of our environment and the wise use of our natural resources. Each of EDF's members has a personal interest in the maintenance of a safe, healthful, productive environment as free from waste substances as is possible. EDF's members have contributed financially to EDF in part so that they may obtain adequate representation of their legally protected environmental interests, which representation they could not otherwise individually afford. Each of EDF's members has under § 101 (c) of NEPA, 'a responsibility to contribute to the preservation and enhancement of the environment,' which responsibility they fulfill in part by becoming a member of and contributing to EDF.

"The increased freight rates and charges in *Ex Parte 281* and the continuance of the underlying rate structure, which discriminate

judge had denied the defendants' motion to dismiss and SCRAP's motion for a temporary restraining order, a statutory three-judge district court was convened pursuant to 28 U. S. C. §§ 2325, 2284, to decide the motion for a preliminary injunction and the cross-motion to dismiss the complaint.

On July 10, 1972, the District Court filed an opinion, 346 F. Supp. 189, and entered an injunction forbidding the Commission "from permitting," and the railroads "from collecting" the 2.5% surcharge "insofar as that surcharge relates to goods being transported for purposes of recycling, pending further order of this court." [10]

---

against movement of secondary (recyclable) materials, will cause EDF members individualized injury and adversely affect them in one or more of their activities and pastimes. Specifically, each EDF member: (i) has been or will be caused to pay more for products in the market place, made more expensive by both the non-use of recycled materials in their manufacture, and the need to use comparatively more energy in processing primary raw materials as opposed to secondary (recyclable) materials; (ii) uses the nation's forests, rivers, streams, mountains, and other natural resources for camping, hiking, fishing, sightseeing, and other recreational and aesthetic purposes. These uses have been and will continue to be adversely affected to the extent that the freight rate structure, as modified thus far in *Ex Parte 281*, encourages destruction of virgin timber, the unnecessary extraction of nonrenewable resources, and the discharge and accumulation of otherwise recyclable materials."

[10] The Court dismissed as moot that part of the complaint relating to the Commission's February 1 order because that order had expired by its own terms on June 5. Since the environmental groups have not appealed from the judgment below, we have before us for review only the District Court's action with regard to the Commission's April 24 order that allowed the surcharge to continue until November 30, 1972.

The Court also concluded that since the Commission had taken no final action with respect to the 4.1% selective increase, the lawfulness of that tariff was not ripe for review. The Court did, however, retain jurisdiction over the case to review the final order of the Commission.

The Court first rejected the contention that the appellees were without standing to sue because they allegedly had no more than "a general interest in seeing that the law is enforced," *id.*, at 195, and distinguished our recent decision in *Sierra Club* v. *Morton*, 405 U. S. 727, on the basis that, unlike the petitioner in *Sierra Club*, the environmental groups here had alleged that their members used the forests, streams, mountains and other resources in the Washington area and that this use was disturbed by the environmental impact caused by nonuse of recyclable goods.

Second, the Court found that its power to grant an injunction was not barred by our decision in *Arrow Transportation Co.* v. *Southern R. Co.*, 372 U. S. 658, 667, where we held that in enacting 49 U. S. C. § 15 (7), Congress had intentionally vested "in the Commission the sole and exclusive power to suspend and [withdrew] from the judiciary any pre-existing power to grant injunctive relief." The Court reasoned that NEPA "implicitly confers authority on the federal courts to enjoin *any* federal action taken in violation of NEPA's procedural requirements . . . so long as the review is confined to a determination as to whether the procedural requisites of NEPA have been followed." 346 F. Supp., at 197 and n. 11.

Finally, turning to the merits, the Court concluded that the Commission's April 24 decision not to suspend the surcharge for the statutory seven-month period was a "major Federal action significantly affecting the quality of the human environment." On the premise that an environmental impact statement is required "whenever the action *arguably* will have an adverse environmental impact," *id.*, at 201, the Court held that "the danger of an adverse impact is sufficiently real to require a statement in this case." *Ibid.*

The District Court declined to stay its injunctive order pending appeal to this Court, and on July 19, 1972, THE

CHIEF JUSTICE, as Circuit Justice for the District of Columbia Circuit, denied applications to stay the preliminary injunction. 409 U. S. 1207. On December 18, 1972, we noted probable jurisdiction of the appeals filed by the United States, the Commission, and the railroads. 409 U. S. 1073.[11]

---

[11] While subsequent events do not bear directly on the validity of the District Court's action in granting the preliminary injunction, they do highlight the problems that hover in the background of this litigation.

On October 4, 1972, the Commission served its report and order in *Ex parte 281* approving, with some exceptions, the general increases filed by the railroads. *Increased Freight Rates and Charges, 1972*, 341 I. C. C. 290. In that report, although the Commission gave extensive consideration to environmental aspects of the rate increases, it declined to include a formal environmental impact statement because it concluded that its actions "will neither actually nor potentially significantly affect the quality of the human environment . . . ." *Id.*, at 314.

The selective increases were to become effective on October 23, 1972, but the Commission delayed until November 12, the effective date for rate increases on recyclable commodities in order to allow the submission of comments by interested parties. Upon the submission of critical comments, the Commission, in an unreported order served on November 8, reopened the rate proceeding in *Ex parte 281* for further evaluation of the rates on recyclable commodities, and ordered the proposed selective tariff increases on those commodities suspended for the full seven-month period authorized by statute—until June 10, 1973. Accordingly, with respect to recyclable commodities on which the proposed selective increase had been suspended, the Commission extended the expiration date of the 2.5% surcharge until June 10, 1973, the expiration date for the suspension of the selective increases. But the Commission acknowledged that the power to collect the surcharge on these recyclable commodities was barred by the preliminary injunction issued by the District Court in the present case and which is the subject of the present appeal. In short, the temporary 2.5% surcharge would have been in effect throughout this period on recyclable commodities but for the District Court's resilient preliminary injunction. Whether the Commission deliberately continued the surcharge beyond the time it would have been supplanted by the selective increases in order to

## II

The appellants challenge the appellees' standing to sue, arguing that the allegations in the pleadings as to stand-

---

give the surcharge and the District Court's injunction continuing effect and thus avoid mooting this case, and whether the Commission acted beyond its powers under 49 U. S. C. § 15 (7) by suspending the selective increases for a second seven-month period and by treating the District Court's injunction as having continuing effect, are questions not raised in this case. No party now maintains that this case is moot. Cf. *Southern Pacific Terminal Co.* v. *Interstate Commerce Commission*, 219 U. S. 498, 515.

Both sets of appellees filed motions in the District Court: SCRAP sought a preliminary injunction against the Commission's October 4 order, and EDF and the other intervening plaintiffs sought leave to file an amended and supplemental complaint and requested other relief. On January 9, 1973, the Court deferred consideration of the EDF motions and denied SCRAP's request for a preliminary injunction. The Court found that as a result of the Commission's November 8 order, neither the selective rate increases nor the temporary surcharge could be assessed on recyclable commodities. Consequently, the Court found, no injunctive relief was justified as to those materials. While the permanent rate increase approved by the Commission in *Ex parte 281* was then being collected on shipments of all other commodities, and although the Commission had concededly failed to file an impact statement, the Court concluded that "the danger of an adverse impact appears to be sufficiently speculative . . . that it would be unsound to grant preliminary relief." The Court continued: "The record indicates that many railroads are in dire financial straits—some on the verge of bankruptcy—and badly need the revenues now being obtained under the Commission's rate increase. The increase amounts to some $340 million per year, and were this revenue flow halted it could not easily be recouped should it later appear that no NEPA statement was necessary." The merits of neither the Commission's October 4 order nor the District Court's January 9 decision are before us, and we therefore express no opinion on them.

On May 7, 1973, the Commission served its final environmental impact statement relating to the selective rate increases on recyclable commodities. It concluded that the proposed increases would have no significant adverse effect on the environment. Contending that

ing were vague, unsubstantiated and insufficient under our recent decision in *Sierra Club* v. *Morton, supra.* The appellees respond that unlike the petitioner in *Sierra Club,* their pleadings sufficiently alleged that they were "adversely affected" or "aggrieved" within the meaning of § 10 of the Administrative Procedure Act (APA), 5 U. S. C. § 702,[12] and they point specifically to the allegations that their members used the forests, streams, mountains and other resources in the Washington Metropolitan Area for camping, hiking, fishing, and sightseeing, and that this use was disturbed by the adverse environmental impact caused by the nonuse of recyclable goods brought about by a rate increase on those commodities. The District Court found these allegations sufficient to withstand a motion to dismiss. We agree.

The petitioner in *Sierra Club,* "a large and long-established organization, with a historic commitment to the cause of protecting our Nation's natural heritage from man's depredations," 405 U. S., at 739, sought a declaratory judgment and an injunction to restrain federal officials from approving the creation of an extensive ski-resort development in the scenic Mineral King Valley of the Sequoia National Forest. The Sierra Club claimed standing to maintain its "public interest" lawsuit because it had "a special interest in the conservation and

---

the impact statement was inadequate, EDF and SCRAP sought to enjoin collection of the selective rate increases. On June 7, 1973, the District Court temporarily enjoined the railroads from collecting the selective increases on recyclable commodities. On June 8, 1973, THE CHIEF JUSTICE, as Circuit Justice for the District of Columbia Circuit, stayed the District Court's injunction pending further order of this Court.

[12] Like the petitioner in *Sierra Club,* the appellees here base their standing to sue upon § 10 of the Administrative Procedure Act (APA), 5 U. S. C. § 702, which provides:

"A person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute, is entitled to judicial review thereof."

the sound maintenance of the national parks, game refuges and forests of the country. . . ." *Id.*, at 730. We held those allegations insufficient.

Relying upon our prior decisions in *Data Processing Services* v. *Camp,* 397 U. S. 150, and *Barlow* v. *Collins,* 397 U. S. 159, we held that § 10 of the APA conferred standing to obtain judicial review of agency action only upon those who could show "that the challenged action had caused them 'injury in fact,' and where the alleged injury was to an interest 'arguably within the zone of interests to be protected or regulated' by the statutes that the agencies were claimed to have violated." 405 U. S., at 733.[13]

In interpreting "injury in fact" we made it clear that standing was not confined to those who could show "economic harm," although both *Data Processing* and *Barlow* had involved that kind of injury. Nor, we said, could the fact that many persons shared the same injury be sufficient reason to disqualify from seeking review of an agency's action any person who had in fact suffered injury. Rather, we explained: "Aesthetic and environmental well-being, like economic well-being, are important ingredients of the quality of life in our society, and the fact that particular environmental interests are shared by the many rather than the few does not make them less deserving of legal protection through the judicial process." *Id.*, at 734. Consequently, neither the fact that the appellees here claimed only a harm to their use and enjoyment of the natural resources of the Wash-

---

[13] As in *Sierra Club*, it is unnecessary to reach any question concerning the scope of the "zone of interests" test or its application to this case. It is undisputed that the "environmental interest" that the appellees seek to protect is within the interests to be protected by NEPA, and it is unnecessary to consider the various allegations of economic harm on which the appellees also relied in their pleadings and which the Government contends are outside the intended purposes of NEPA.

ington area, nor the fact that all those who use those resources suffered the same harm, deprives them of standing.

In *Sierra Club*, though, we went on to stress the importance of demonstrating that the party seeking review be himself among the injured, for it is this requirement that gives a litigant a direct stake in the controversy and prevents the judicial process from becoming no more than a vehicle for the vindication of the value interests of concerned bystanders. No such specific injury was alleged in *Sierra Club*. In that case the asserted harm "will be felt directly only by those who use Mineral King and Sequoia National Park, and for whom the aesthetic and recreational values of the area will be lessened by the highway and ski resort," *id.*, at 735, yet "[t]he Sierra Club failed to allege that it or its members would be affected in any of their activities or pastimes by the . . . development." *Ibid.* Here, by contrast, the appellees claimed that the specific and allegedly illegal action of the Commission would directly harm them in their use of the natural resources of the Washington Metropolitan Area.

Unlike the specific and geographically limited federal action of which the petitioner complained in *Sierra Club*, the challenged agency action in this case is applicable to substantially all of the Nation's railroads, and thus allegedly has an adverse environmental impact on all the natural resources of the country. Rather than a limited group of persons who used a picturesque valley in California, all persons who utilize the scenic resources of the country, and indeed all who breathe its air, could claim harm similar to that alleged by the environmental groups here. But we have already made it clear that standing is not to be denied simply because many people suffer the same injury. Indeed some of the cases on which we relied in *Sierra Club* demonstrated the patent fact that persons

across the Nation could be adversely affected by major governmental actions. See, *e. g., Environmental Defense Fund* v. *Hardin*, 428 F. 2d 1093, 1097 (interests of consumers affected by decision of Secretary of Agriculture refusing to suspend registration of certain pesticides containing DDT); *Reade* v. *Ewing*, 205 F. 2d 630, 631–632 (interests of consumers of oleomargarine in fair labeling of product regulated by Federal Security Administration). To deny standing to persons who are in fact injured simply because many others are also injured, would mean that the most injurious and widespread Government actions could be questioned by nobody. We cannot accept that conclusion.

But the injury alleged here is also very different from that at issue in *Sierra Club* because here the alleged injury to the environment is far less direct and perceptible. The petitioner there complained about the construction of a specific project that would directly affect the Mineral King Valley. Here, the Court was asked to follow a far more attenuated line of causation to the eventual injury of which the appellees complained—a general rate increase would allegedly cause increased use of nonrecyclable commodities as compared to recyclable goods, thus resulting in the need to use more natural resources to produce such goods, some of which resources might be taken from the Washington area, and resulting in more refuse that might be discarded in national parks in the Washington area. The railroads protest that the appellees could never prove that a general increase in rates would have this effect, and they contend that these allegations were a ploy to avoid the need to show some injury in fact.

Of course, pleadings must be something more than an ingenious academic exercise in the conceivable. A plaintiff must allege that he has been or will in fact be perceptibly harmed by the challenged agency action,

not that he can imagine circumstances in which he could be affected by the agency's action. And it is equally clear that the allegations must be true and capable of proof at trial. But we deal here simply with the pleadings in which the appellees alleged a specific and perceptible harm that distinguished them from other citizens who had not used the natural resources that were claimed to be affected.[14] If, as the railroads now assert, these allegations were in fact untrue, then the appellants should have moved for summary judgment on the standing issue and demonstrated to the District Court that the allegations were sham and raised no genuine issue of fact.[15] We cannot say on these pleadings that the ap-

[14] The Government urges us to limit standing to those who have been "significantly" affected by agency action. But, even if we could begin to define what such a test would mean, we think it fundamentally misconceived. "Injury in fact" reflects the statutory requirement that a person be "adversely affected" or "aggrieved," and it serves to distinguish a person with a direct stake in the outcome of a litigation—even though small—from a person with a mere interest in the problem. We have allowed important interests to be vindicated by plaintiffs with no more at stake in the outcome of an action than a fraction of a vote, see *Baker* v. *Carr*, 369 U. S. 186; a five dollar fine and costs, see *McGowan* v. *Maryland*, 366 U. S. 420; and a $1.50 poll tax, *Harper* v. *Virginia Bd. of Elections*, 383 U. S. 663. While these cases were not dealing specifically with § 10 of the APA, we see no reason to adopt a more restrictive interpretation of "adversely affected" or "aggrieved." As Professor Davis has put it: "The basic idea that comes out in numerous cases is that an identifiable trifle is enough for standing to fight out a question of principle; the trifle is the basis for standing and the principle supplies the motivation." Davis, Standing: Taxpayers and Others, 35 U. Chi. L. Rev. 601, 613. See also K. Davis, Administrative Law Treatise, §§ 22.09–5 to 22.09–6 (1970 Supplement).

[15] The railroads object to the fact that the allegations were not more precise—that no specific "forest" was named, that there was no assertion of the existence of any lumbering camp or other extractive facility in the area. They claim that they had no way to answer such allegations which were wholly barren of specifics. But, if that

pellees could not prove their allegations which, if proved, would place them squarely among those persons injured in fact by the Commission's action, and entitled under the clear import of *Sierra Club* to seek review. The District Court was correct in denying the appellants' motion to dismiss the complaint for failure to allege sufficient standing to bring this lawsuit.

## III

We need not reach the issue whether, under conventional standards of equity, the District Court was justified in issuing a preliminary injunction, because we have concluded that the Court lacked jurisdiction to enter an injunction in any event.

The District Court enjoined the Commission from "permitting," and the railroads from "collecting," the 2.5% interim surcharge on recyclable commodities. Finding that NEPA implicitly conferred authority "on the federal courts to enjoin *any* federal action taken in violation of NEPA's procedural requirements," 346 F. Supp., at 197, it concluded that our decision in *Arrow Transportation Co.* v. *Southern R. Co., supra,* did not affect judicial power to issue an injunction in the circumstances of this case. We cannot agree.

In *Arrow,* the Commission had suspended a railroad's proposed rates for the statutory seven-month period, and the railroad had voluntarily deferred the proposed rate

---

were really a problem, the railroads could have moved for a more definite statement, see Rule 12 (e), Fed. Rule Civ. Proc., and certainly normal civil discovery devices were available to the railroads.

Similarly, the District Court cannot be faulted for failing to take evidence on the issue of standing. This case came before the Court on motions to dismiss and for a preliminary injunction. If the railroads thought that it was necessary to take evidence, or if they believed summary judgment was appropriate, they could have moved for such relief.

for an additional five months. When the Commission had not reached a final decision within that period, the railroad announced its intent to adopt the new rates. In a suit brought to enjoin the railroad from effectuating that change, we held that the courts were without power to issue such an injunction. From the language and history of § 15 (7) of the Interstate Commerce Act, we concluded that Congress had vested exclusive power in the Commission to suspend rates pending its final decision on their lawfulness, and had deliberately extinguished judicial power to grant such relief. The factual distinctions between the present case and *Arrow* are inconsequential.

It is true that the injunction in *Arrow* was sought after the statutory seven-month period had expired and thus represented an attempt to extend judicially the suspension period, while here the injunction was issued during the suspension period. But *Arrow* was grounded on the lack of power in the courts to grant any injunction before the Commission had finally determined the lawfulness of the rates, and that holding did not depend on the fact that the availability of the Commission's power of suspension had passed. Indeed, the federal court decisions cited and approved in *Arrow* involved instances where the courts had been asked to enjoin rates *during* the statutory seven-month period. See, *e. g., M. C. Kiser Co.* v. *Central of Georgia R. Co.,* 236 F. 573, aff'd, 239 F. 718; *Freeport Sulphur Co.* v. *United States,* 199 F. Supp. 913; *Bison S. S. Corp.* v. *United States,* 182 F. Supp. 63; *Luckenbach S. S. Co.* v. *United States,* 179 F. Supp. 605, 609–610, vacated in part as moot, 364 U. S. 280; *Carlsen* v. *United States,* 107 F. Supp. 398.

Similarly, there is no significance in the fact that, unlike *Arrow,* the injunction in this case ran against

the Commission as well as the railroads. The only way in which the Commission could comply with the Court's order would be to exercise its power of suspension and suspend the surcharge. The injunction constitutes a direct interference with the Commission's discretionary decision whether or not to suspend the rates. It would turn *Arrow* into a sheer formality and effectively amend § 15 (7) if a federal court could accomplish by injunction against the Commission what it could not accomplish by injunction directly against the railroads. And again, the federal court decisions on which *Arrow* relied were for the most part cases in which the courts had held that they were without power to compel the Commission to grant a rate suspension. See, *e. g., Bison S. S. Corp.* v. *United States, supra; Luckenbach S. S. Co.* v. *United States, supra; Carlsen* v. *United States, supra;* cf. *Freeport Sulphur Co.* v. *United States, supra.*[16]

Thus the only arguably significant distinction between the present case and *Arrow* is that here the Commission allegedly failed to comply with NEPA. However, we cannot agree with the District Court that NEPA has amended § 15 (7) *sub silentio* and created an implicit

---

[16] EDF suggests that the April 24 order of the Commission was in fact a final order finding the surcharge "just and reasonable," not simply a refusal to suspend the surcharge. But the Commission's reference to the "just and reasonable" nature of the surcharge was a preliminary assessment commonly made in suspension orders. See, *e. g.,* the suspension orders quoted in *Naph-Sol Refining Co.* v. *United States,* 269 F. Supp. 530, 531; *Oscar Mayer & Co.* v. *United States,* 268 F. Supp. 977, 978–979. It did not represent a final determination by the Commission that any particular rate was just and reasonable. Indeed the Commission made it clear in its February 1 order that the surcharge was not considered a prescribed rate within the meaning of *Arizona Grocery Co.* v. *Atchison, T. & S. F. R. Co.,* 284 U. S. 370, and was subject to complaint and investigation under the Act.

exception to *Arrow* so that judicial power to grant injunctive relief in this case has been revived.[17] NEPA, one of the recent major federal efforts at reversing the deterioration of the country's environment, declares "that it is the continuing policy of the Federal Government . . . to use all practicable means and measures . . . in a manner calculated to foster and promote the general welfare, to create and maintain conditions under which man and nature can exist in productive harmony, and fulfill the social, economic, and other requirements of present and future generations of Americans." 42 U. S. C. § 4331. To implement these lofty purposes, Congress imposed a number of responsibilities upon federal agencies, most notably the requirement of producing a detailed environmental impact statement for "major Federal actions significantly affecting the quality of the

---

[17] An alternative ground for avoiding the *Arrow* decision, which was suggested but not relied on by the District Court, was that the surcharge here was an "agency-made" rate, not a "carrier-made" rate. *Moss* v. *CAB*, 430 F. 2d 891, which was cited by the Court is, however, plainly inapposite. There the CAB suspended the rates proposed by the carriers, but suggested in their place "a complete and innovative scheme for setting all passenger rates for the United States." *Id.*, at 899. It was clear that when the carriers filed the rates suggested by the Board they would not be suspended. "Even a cursory reading of the order makes it clear that the Board told the carriers what rates to file, it set forth a step-by-step formula requiring major changes in rate-making practices and in rates which it expected the carriers to adopt." *Id.*, at 899–900. Here, by contrast, the level and structure of the rates were proposed entirely by the carriers. While the Commission suggested an expiration date for the surcharge, this was simply to make the surcharge expire when the general selective increases went into effect. This expiration date and the other standard conditions attached to the Commission's refusal to suspend the surcharge did not, in any meaningful sense, transform the carrier-made rate into a Commission-made rate.

human environment." 42 U. S. C. § 4332 (C).[18] But nowhere, either in the legislative history or the statutory language, is there any indication that Congress intended to restore to the federal courts the power temporarily to suspend railroad rates, a power that had been clearly taken away by § 15 (7) of the Interstate Commerce Act.

The statutory language in fact indicates that NEPA was not intended to repeal by implication any other statute. Thus, 42 U. S. C. § 4335 specifies that "The policies and goals set forth in [NEPA] are supplementary to those set forth in existing authorizations of Federal agencies," and 42 U. S. C. § 4334 instructs that the Act "shall [not] in any way affect the specific statutory obligations of any Federal agency . . . ." Rather than providing for any wholesale overruling of prior law, NEPA requires all federal agencies to review their "present statutory authority, administrative regulations, and current policies and procedures for the purpose of determining whether there are any deficiencies or inconsistencies therein which prohibit full compliance with the purposes and provisions of [NEPA] and shall propose to the President . . . such measures as may be necessary to bring their authority and policies into conformity with the intent, purposes, and procedures set forth in [NEPA]." 42 U. S. C. § 4333. It would be anomalous if Congress had provided at one and the same time that federal agencies, which have the primary responsibility for the implementation of NEPA,[19] must comply with present law and ask for any necessary new

---

[18] See n. 8, *supra*.

[19] See *Greene County Planning Board* v. *FPC*, 455 F. 2d 412, 420; *Calvert Cliffs' Coordinating Comm'n* v. *United States Atomic Energy Comm'n*, 449 F. 2d 1109, 1119; *City of New York* v. *United States*, 337 F. Supp. 150, 160; *Cohen* v. *Price Comm'n*, 337 F. Supp. 1236, 1241.

legislation, but that the courts may simply ignore what we described in *Arrow* as "a clear congressional purpose to oust judicial power . . . ." 372 U. S., at 671 n. 22.[20]

The District Court pointed to nothing either in the language or history of NEPA that suggests a restoration of previously eliminated judicial power. While it relied primarily on the decisions of the Court of Appeals for the District of Columbia Circuit in *Calvert Cliffs' Coordinating Comm'n* v. *United States Atomic Energy Comm'n*, 449 F. 2d 1109, and *Committee for Nuclear Responsibility, Inc.* v. *Seaborg*, 463 F. 2d 783, neither case supports an injunction under the circumstances of this case. *Calvert Cliffs* held that a federal court had power to review rules promulgated by the Atomic Energy Commission, and there the court ordered further consideration of the rules on the ground that there had not been compliance with NEPA. In *Committee for Nuclear Responsibility* it was held that federal courts had jurisdiction to consider whether an executive decision to conduct a nuclear test had satisfied the procedural requirements of NEPA. The question here, however, is

[20] The argument that NEPA implicitly restored to the courts the injunctive power that § 15 (7) had divested is similar to a contention rejected in *Arrow* itself. There the petitioners claimed that congressional adoption of the National Transportation Policy, 54 Stat. 899, had implicitly altered § 15 (7). They claimed that the proposed new railroad rates would drive the barge lines out of existence, contrary to the congressional declaration of concern for the protection of water carriers threatened by rail competition. The Court concluded that "nothing in the National Transportation Policy, enacted many years after . . . § 15 (7), indicates that Congress intended to revive a judicial power which . . . was extinguished when the suspension power was vested in the Commission." 372 U. S., at 673. In addition, the Court noted that, as is also true with NEPA, the mandate was directed not to the Courts but to the Commission. There is nothing about NEPA that makes it any more amenable for finding an implicit amendment of § 15 (7), than the National Transportation Policy was.

not whether there is general judicial power to determine if an agency has complied with NEPA, and to grant equitable relief if it has not, cf. *Arrow Transportation Co.* v. *Southern R. Co., supra,* at 671 n. 22; *Scripps Howard Radio Inc.* v. *FCC,* 316 U. S. 4, but rather whether in a specific context NEPA *sub silentio* revived judicial power that had been explicitly eliminated by Congress. *Calvert Cliffs'* and *Committee for Nuclear Responsibility* have nothing to say on this issue, for neither was concerned with a specific statute that restricts the power of the federal courts to grant injunctions.[21]

Our conclusion that the District Court lacked the power to grant the present injunction is confirmed by the fact that each of the policies that we identified in *Arrow* as the basis for § 15 (7) would be substantially undermined if the courts were found to have suspension powers simply because noncompliance with NEPA was alleged.

First, *Arrow* found that the Commission had been granted exclusive suspension powers in order to avoid the diverse results that had previously been reached by the courts. District courts had differed as to the existence and scope of any power to grant interim relief, with the consquence that the uniformity of rates had been jeopardized, and different shippers, carriers, and areas of the country had been subjected to disparate treatment. Similarly, since a suit to enjoin a national rate increase on NEPA grounds could be brought in any federal district court in the country, see 28 U. S. C. §§ 2284, 2321–2325, the result might easily be that the courts would "[reach] diverse results, . . . [engendering] confusion

[21] Indeed *Calvert Cliffs'* indicated that the requirements of § 102 of NEPA, see n. 8, *supra,* did not have to be complied with, if such compliance was precluded by another statutory provision. 449 F. 2d, at 1115. And *Committee for Nuclear Responsibility,* in another context, endorsed a principle, equally applicable here, that "repeal by implication is disfavored." 463 F. 2d, at 785.

and [producing] competitive inequities." 372 U. S., at 663. In short, a rate increase allowed in New York might be disallowed in New Jersey.

Second, we stressed in *Arrow* that § 15 (7) represents a careful accommodation of the various interests involved. The suspension period was limited as to time to prevent excessive harm to the carriers, for the revenues lost during that period could not be recouped from the shippers. On the other hand, Congress was aware that if the Commission did not act within the suspension period, then the new rates would automatically go into effect and the shippers would have to pay increased rates that might eventually be found unlawful. To mitigate this loss, Congress authorized the Commission to require the carriers to keep detailed accounts and eventually to repay the increased rates if found unlawful. To allow judicial suspension for noncompliance with NEPA, would disturb this careful balance of interests. A railroad may depend for its very finanical life on an increased rate, and the rate may be perfectly just and reasonable. Granting an injunction against that rate based on the Commission's alleged noncompliance with NEPA, although the Commission had determined not to suspend the rate, would deprive the railroads of vitally needed revenues and result in an unjustified windfall to shippers.

Finally, we found in *Arrow* that any survival of a judicial power to grant interim injunctive relief would represent an undesirable interference with the orderly exercise of the Commission's power of suspension. Similarly, to grant an injunction in the present context, even though not based upon a substantive consideration of the rates, would directly interfere with the Commission's decision as to *when* the rates were to go into effect, and would ignore our conclusion in *Arrow* that "Congress meant to foreclose a judicial power to interfere

with the *timing* of rate changes which would be out of harmony with the uniformity of rate *levels* fostered by the doctrine of primary jurisdiction." *Id.*, at 668. As the Court of Appeals for the Second Circuit explained in *Port of New York Authority* v. *United States*, 451 F. 2d 783, 788, where, on the basis of alleged noncompliance with NEPA, an injunction was sought against a Commission order refusing to suspend rates:

> "The basis of the decision in *Arrow*—that to permit judicial interference with the Commission's suspension procedures would invite the very disruption in the orderly review of the lawfulness of proposed tariffs that Congress meant to preclude—applies with equal force to the issue now before us."

Accordingly, because the District Court granted a preliminary injunction suspending railroad rates when it lacked the power to do so,[22] its judgment must be re-

[22] In view of our conclusion that there was no power to grant the preliminary injunction, it is unnecessary for us to reach the other questions posed by the parties. For example, the Government and the railroads urge that, because of the pressures of time, an environmental impact statement is not required at the suspension stage of a rate proceeding, and, in any event, a decision by the Commission whether or not to suspend rates is not subject to judicial review. See *Port of New York Authority*, 451 F. 2d 783; *Oscar Mayer & Co.* v. *United States*, 268 F. Supp. 977; *M. C. Kiser Co.* v. *Central of Georgia R. Co., supra; Freeport Sulphur Co.* v. *United States, supra; Luckenbach S. S. Co.* v. *United States, supra; Carlsen* v. *United States, supra.* The appellees in turn contend that some compliance with NEPA is possible at the suspension stage, and that such compliance is required if the statute is to be enforced "to the fullest extent possible." See 42 U. S. C. § 4332. And they urge that there is or should be an exception to the general principle of nonreviewability of suspension decisions for those cases where the Commission has acted beyond its statutory authority, or in violation of a clear statutory command or a procedural require-

versed and the case remanded to that court for further proceedings consistent with this opinion.

*It is so ordered.*

MR. JUSTICE POWELL took no part in the consideration or decision of these cases.

---

ment, a standard that the appellees view as broad enough to encompass alleged noncompliance with NEPA. See *Naph-Sol Refining Co.* v. *United States,* 269 F. Supp. 530, 532; *Oscar Mayer & Co.* v. *United States, supra,* at 982 (Doyle, J., concurring); *Long Island R. Co.* v. *United States,* 193 F. Supp. 795. We express no view on any of these issues.

# SUPREME COURT OF THE UNITED STATES

Nos. 72–535 AND 72–562

| | |
|---|---|
| United States and Interstate Commerce Commission, Appellants, 72–535 *v.* Students Challenging Regulatory Agency Procedures (SCRAP) et al. | On Appeals from the United States District Court for the District of Columbia. |
| Aberdeen and Rockfish Railroad Company et al., Appellants, 72–562 *v.* Students Challenging Regulatory Agency Procedures (SCRAP) et al. | |

[June 18, 1973]

MR. JUSTICE BLACKMUN, with whom MR. JUSTICE BRENNAN joins, concurring.

I join the Court's judgment and its opinion, but because of the presence of the first sentence of Part III of the opinion, and to avoid any misunderstanding as to my posture, I add a few words.

For the reasons stated in my dissenting opinion in *Sierra Club* v. *Morton*, 405 U. S. 727, 755 (1972), I would hold that the appellees here have standing to maintain this action based on their allegations of harm to the environment resulting from the Commission's order of April 24, 1972. And in evaluating whether injunctive relief is warranted, I would not require that the appellees, in their individual capacities, prove that they

in fact were injured. Rather, I would require only that appellees, as responsible and sincere representatives of environmental interests, show that the environment would be injured in fact and that such injury would be irreparable and substantial.

# SUPREME COURT OF THE UNITED STATES

Nos. 72-535 AND 72-562

| | |
|---|---|
| United States and Interstate Commerce Commission, Appellants,<br>72-535 v.<br>Students Challenging Regulatory Agency Procedures (SCRAP) et al.<br><br>Aberdeen and Rockfish Railroad Company et al., Appellants,<br>72-562 v.<br>Students Challenging Regulatory Agency Procedures (SCRAP) et al. | On Appeals from the United States District Court for the District of Columbia. |

[June 18, 1973]

MR. JUSTICE DOUGLAS, dissenting in part.

I

These cases present important environmental problems. They concern ratemaking for the shipment of litter for recycling. Paper, glass, and metals are the main items in today's garbage.[1] As indicated by the Bureau of Mines in Appendix I to this dissent, America's

[1] In a Bureau of Mines' survey, it was established that metals and glass account for approximately 75 weight-percent of the residues in municipal incinerator waste. Economics of Recycling Metals and Minerals from Urban Refuse, Bureau of Mines Technical Progress Report, April 1971, p. 2. From these materials, if recycled, familiar products such as bottles, newspapers, iron ingots, paper pulp, fuel oil, and methane gas can be manufactured. In addition, new products are being developed, such as glassphalt for street paving, insulation, glass wool, and glass bricks, in various colors that meet specifica-

method of disposing of garbage is either to use it for landfill or to put it first through incinerators and then to bury the residue. Sorting and recycling have several environmental impacts: (1) reduction in the use of incinerators lessens air pollution; (2) establishing or encouraging removal of litter from the landscape; (3) recycling saves both renewable and nonrenewable resources. As respects the last, the tons of paper that are recycled, rather than burned, can be translated into the number of standing trees that need not be cut for pulp the next year; the metals recycled protect our remaining nonrenewable supplies of ore, and so on.

Rates fixed so as to encourage vast shipments of litter are, therefore, perhaps the most immediate and dramatic illustration of a policy which will encourage protection of the environment against several erosive conditions.[2]

---

tions for "severe weather"-facing-brick. Economics of Recycling Metals and Minerals from Urban Refuse, *supra*, p. 7.

This project was launched under the Resource Recovery Act of 1970, 84 Stat. 1227, 42 U. S. C. § 3251 *et seq.*, under which the Secretary of HEW was authorized to provide technical and financial assistance in planning and developing resource recovery and solid waste disposal programs.

For a detailed account of a Resource Recovery Mill see Ross, How to Succeed in Recycling. Environmental Quality Magazine, June 1973, p. 51.

[2] The necessity of reasonable trasportation rates is even more apparent when it is realized that the volume of residue which is processed at a major recycling plant is between 250 and 1,000 tons per day. (Economics of Recycling Metals and Minerals from Urban Refuse, Bureau of Mines Technical Progress Report, April 1971, p. 1.) Massive bulk transportation is therefore essential to these plant operations.

The problem is even more critical in urban areas where there is a high concentration of solid waste being generated and transportation to outlying recycling plants is a major cost factor. In 1968 a national survey found that an average of 8.2 pounds of waste per capita were collected daily in urban areas; this figure has now risen to 9 pounds. If present trends continue, this figure could be as high as 12 pounds in another 10 years. In our urban areas as a whole,

I would, therefore, affirm the eminently responsible decision of the District Court. 346 F. Supp. 189.

The Environmental Protection Act of 1969, 83 Stat. 856, 42 U. S. C. § 4321 *et seq.*, declares a congressional policy:

> ". . . which will encourage productive and enjoyable harmony between man and his environment; to promote efforts which will prevent or eliminate damage to the environment and biosphere and stimulate the health and welfare of man; to enrich the understanding of the ecological systems and natural resources important to the Nation; and to establish a Council on Environmental Quality."

That broad policy is further expounded in § 4331 (b) to include *inter alia,* the objective that "the nation may . . . (2) assure for all Americans safe, healthful, productive, and esthetically and culturally pleasing surroundings . . . and (6) enhance the quality of renewable resources and depletable services."

The Government urges that the petitioners do not have standing to challenge the administrative determination of railroad freight rate increases. SCRAP alleged in its amended complaint that its members suffered environmental and economic injury as a result of the alleged increase, because the increase diminished the total amount of waste recycling in the United States, and made those products, which were in fact manufactured from the waste materials after the rate increase, more expensive in the marketplace. In addition, SCRAP alleged that each of its members in fact use the "forests, rivers, streams, mountains, and other natural resources . . ." for recreational purposes, and these uses were adversely affected because the Commission's rate increases discourage the

---

the solid waste generated is fast approaching a ton a year for each man, woman, and child. Science and Public Affairs, Energy Conservation and Waste Recycling, April 1973, p. 13, 17.

reuse of recyclable commodities, such as bottles and cans, and encourage the depletion of natural resources.

In *Sierra Club* v. *Morton,* 405 U. S. 727, 734, this Court stated that, "We do not question that [environmental] harm may amount to an 'injury in fact' sufficient to lay the basis for standing under § 10 of the APA. Aesthetic and environmental well-being, like economic well-being, are important ingredients of the quality of life in our society, and the fact that particular environmental interests are shared by the many rather than the few does not make them less deserving of legal protection through the judicial process." The members of SCRAP, have clearly alleged an "injury in fact" to the environment and to their own personal continued use of it.

"There is nothing unusual or novel in granting the consuming public standing to challenge administrative actions." (*Office of Communication of United Church of Christ* v. *FCC,* — U. S. App. D. C.—, 359 F. 2d 994.) This Court has indicated that where "statutes are concerned, the trend is toward enlargement of the class of people who may protest administrative action." (*Data Processing Service* v. *Camp,* 397 U. S. 150, 154.)

Littering is a commonplace phenomenon that affects every person, almost everywhere. By reports and writings we know that littering defaces mountain trails, alpine meadows, and even our highest peaks. Those in the valleys are often almost inundated with litter. Where a river is polluted and a person is dependent on it for drinking water, I suppose there would not be the slightest doubt that he would have standing in court to present his claim. I also suppose there is not the slightest doubt that where smog settles on a city, any person who must breathe that air or feel the sulphuric acid forming in his eyes, would have standing in court to present his claim. I think it is equally obvious that any resident

of an area whose paths are strewn with litter, whose parks, or picnic grounds are defaced by it has standing to tender his complaint to the Court. *Sierra Club* v. *Morton, supra,* would seem to cover this case, for littering abetted by the failure to recycle would clearly seem to implicate residents to whom "the aesthetic and recreational vaues of the area" are important. *Id.,* at 735. For the reasons stated in my opinion in *Sierra Club* v. *Morton, supra,* I agree with the Court that appellees have standing, but like MR. JUSTICE BLACKMUN, I would not require appellees, in their individual capacity, to prove injury in fact. As MR. JUSTICE BLACKMUN states, it should be sufficient if appellees, "as responsible and sincere representatives of environmental interests, show that the environment would be injured in fact. . . ."

## II

The Council on Environmental Quality (CEQ), created in the executive office of the President, 42 U. S. C. § 4342, estimated in 1969 that this Nation produced more than 4.3 billion tons of solid refuse, including about 30 million tons of paper, 30 million tons of industrial fly ash, 15 million tons of scrap metal, 4 million tons of plastics, 100 million automobile tires, 30 billion bottles, 60 billion cans, and millions of discarded automobiles and appliances. First Annual Report of CEQ, Aug. 1970, pp. 107–113. It reported that while most of the secondary material could be reused as a replacement for virgin material, only a small fraction was recycled. *Ibid.* One of the reasons for the absence of recycling was the high cost both of collection of the material and the transportation costs. *Ibid.*

As noted, one of the purposes of the Act was to "enhance the quality of renewable resources and approach the maximum attainable recycling of depletable re-

sources." 42 U. S. C. § 4331 (b)(6). On October 9, 1970, Chairman Russell Train of CEQ wrote the Interstate Commerce Commission as follows:

> "The Council on Environmental Quality is deeply concerned with all facets of environmental quality. Solid waste disposal is one important aspect of the total pollution problem, and recycling is a new and desirable alternative to solid waste disposal which the Council strongly supports. The degree to which this technique will be used depends almost entirely on economics. Transportation costs, to the degree they increase secondary or scrap materials costs compared to the raw materials with which they compete, act as a disincentive to recycling. The Council believes that several rail haul costs biases currently exist and would like to discuss these cases with you. . . . In general, across-the-board percentage increases only widen existing price biases against secondary materials. Also, these increases raise the costs of doing business which can hinder the salvage and reclamation industry. In light of the President's concern with environmental quality, the growing problems of solid waste and the importance of recycling to alleviating them, I would like to express the Council's hope that the Interstate Commerce Commission's actions on the key issue of scrap material transportation rates will be consistent with the Nation's environmental quality goals."

In December 1971 substantially all the railroads filed with the Commission a request to impose a 2.5% surcharge on virtually all freight. The procedural details which followed are not presently material. Suffice it to say that shippers of recyclable materials submitted verified statements in support of their view that rate increases

would intensify the disincentives to shipment and use of recyclable materials. Thus the Institute for Scrap Iron and Steel submitted a study showing:

> "(1) Present scrap markets are retarded because of transport rates which encourage the usage of iron ore. (2) Future scrap markets are being affected because new investment that would logically be directed to scrap-intensive steelmaking is diverted because of the existing freight rate structure to ore-intensive steelmaking. (3) Iron ore (a limited domestic natural resource) is being exploited when it can and should be conserved. (4) Some scrap iron that should be recycled is unable to move, thus the environment is despoiled by unnecessary accumulations of solid metallic waste."

The Commission instituted a proceeding concerning the guidelines which environmental impact statements required under the Act should follow. 339 I. C. C. 508. A spokesman for the eastern roads filed an impact statement which said that "any possible adverse environmental impact in the form of reduced movements of commodities by rail will come only if we fail to provide adequate and efficient service" and that the need of the railroads to that end was for increased revenues. Appellees filed a protest and a request for a suspension of the proposed surcharge alleging that the present railroad rate structure discourages the movement of "recyclable" goods and that the surcharge would further discourage recycling.

The Commission, allowing the surcharge for a limited period, found that it would "have no significant adverse effect in the movement of traffic by railway or on the quality of the human environment" within the meaning of the 1969 Act. 340 I. C. C. 358; 341 I. C. C. 287.

Chairman Train of CEQ protested to the Commission:

"It is understandable that difficulties will be encountered in quantifying the environmental consequences of an incremental freight rate increase on recyclable materials. In our view, however, these consequences must be assessed in the light of the rate disparity between secondary and primary materials that gives rise to the problem in the first place. This disparity is a matter of an entirely different magnitude, calling for a thorough environmental assessment as a precondition to determining whether subsequent incremental increases require additional environmental impact statements. . . . Clearly at some point increases which might be individually insignificant become cumulatively significant. In addition, the claim that freight rates on recycled products must be increased to respond to 'emergency' revenue needs pending completion of the required, overall environmental evaluation, loses much of its force as months turn into years and the basic investigation remains uncompleted. Finally, even the 'emergency' argument itself, however legitimate, in no way forecloses the consideration of alternatives which would both meet revenue needs and at the same time avoid further potential environmental damage while the basic rate structure issue is being resolved. Alternatives of this sort were, in fact, suggested in the partial dissenting opinions of Commissioners Brown and Deason [who would have denied approval of increases for recyclable commodities], with no indication in the Commission's majority report that such measures would not have been sufficient to meet the revenue needs relied on to justify the rate increases. . . . In summary, the Council feels that the basic environmental issues related to the existing freight rate structure and

changes thereto, must be evaluated in a logical, analytical and timely fashion in compliance with the requirements of the National Environmental Policy Act. The Commission's actions to date appear to be inconsistent with the objectives of NEPA, and the analyses undertaken to date by the Commission appear to offer an inadequate basis from which to draw conclusions concerning the impact of freight rates on recycling and enviromental quality. Our staff is available to discuss the NEPA procedural issues as well as to assist in structuring the analytical work required to assess adequately the environmental impact of freight rates."[3]

The three-judge District Court held that the conclusion of the Commission that the rate increase would have "no significant adverse effect" on the environment within the meaning of EPA was "transparent" and "a ruse." 346 F. Supp., at 201. This leads to an analysis of § 102 of EPA.[4]

---

[3] In his report before the Senate, Senator Jackson, as one of the three most responsible for NEPA, stated: "To insure that the policies and goals defined in this act are infuesed into the ongoing programs and actions of the Federal Government, the act also establishes some important 'action-forcing' procedures. Section 102 authorizes and directs all Federal agencies, to the fullest extent possible, to administer their existing laws, regulations, and policies in conformance with the policies set forth in this act. It also directs all agencies to assure consideration of the environmental impact of their actions in decision-making. It requires agencies which propose actions to consult with appropriate Federal and State agencies having jurisdiction or expertise in environmental matters and to include any comments made by these agencies which outline the environmental considerations involved with such proposals.

"Taken together, the provisions of section 102 directs [*sic*] any Federal agency which takes action that it must take into account environmental management and environmental quality considerations." (Congressional Record—Senate, Dec. 20, 1969, p. 40416.)

[4] The totality of § 102 is so important to this litigation that I have set it forth in Appendix II to this dissent.

That section is directed to "all agencies of the Federal Government" which of course includes the Interstate Commerce Commission. It directs the agency to interpret and administer "the policies, regulations and public laws" which it administers "to the fullest extent possible" in accordance with the policies of EPA. It directs the agency[5] to include in "major Federal actions significantly affecting the quality of the human environment" a detailed statement "by the responsible official on" "(i) the environmental impact of the proposed action, (ii) any adverse environmental effects which cannot be avoided should the proposal be implemented, (iii) alternatives to the proposed action, (iv) the relationship between local short-term uses of man's environment and the maintenance and enhancement of long-term productivity, and (v) any irreversable and irretrievable commitments of resources which would be involved in the proposed action should it be implemented. . . .

"Prior to making any detailed statement, the responsible Federal official shall consult with and obtain the comments of any Federal agency which has jurisdiction by law or special expertise with respect to any environmental impact involved. Copies of such statement and the comments and views of the appropriate Federal, State, and local agencies, which are authorized to develop and enforce environmental standards, shall be made available to the President, the Council on Environmental Quality and to the public as provided by section

---

[5] Senator Jackson, one of the three most responsible for NEPA recently was reported as saying:

"We expected Section 102 of the act which requires environmental impact statements and analysis of alternatives for all major federal actions significantly affecting the quality of the human environment to force the agencies to move. . . . We did not anticipate that it would be private parties through the courts that would force the compliance. This is what has made it work." Christian Science Monitor, Feb. 28, 1973, p. —.

552 of Title 5, and shall accompany the proposal through the exciting agency review processes."

Rates affecting litter, like rates affecting other commodities, obviously are relevant to the ease and expedition with which they will be transported. To get the litter to appropriate recycling plants in the quantities needed to protect our fast depleting forests and our nonrenewable resources [6] and to relieve our landscape of the litter that plagues us may need special incentive rates.

The Conference Report 91–76J makes clear that no agency of the Federal Government is exempt and that each should comply unless existing law applicable to the agency "expressly prohibits or makes full compliance with one of the directives impossible." The Report states:

> "The purpose of the new language is to make it clear that each agency of the Federal Government shall comply with the directives set out in such subparagraphs (A) through (H) unless the existing law applicable to such agency's operations expressly prohibits or makes full compliance with one of the directives impossible. If such is found to be the case, then compliance with the particular directive is not immediately required. However, as to other activities of that agency, compliance is required. Thus, it is the intent of the conferees that the provision 'to the fullest extent possible' shall not be used by any Federal agency as a means of avoiding compliance with the directives set out in section 102. Rather, the language in section 102 is intended to assure that all agencies of the Federal Government shall

[6] Waldo E. Smith of the American Geophysical Union recently stated: "The total supply of most metals is sharply limited; even now we must dig deeper, go farther, and use lower grade ores. No optimism is justified here. The supply can be extended substantially by intelligent recycling, which should be an important by-product of our cleaning up to maintain a clean environment." Resources and Long-Forecasts, Science & Public Affairs, May 1973, 21, 22.

> comply with the directives set out in said section 'to the fullest extent possible' under their statutory authorizations and that no agency shall utilize an excessively narrow construction of its existing statutory autorizations to avoid compliance." 2 U. S. Code Cong. & Adm. News, 91st Cong., 1st Sess. 1969, p. 2770.

The District Court, acting responsibly in light of the broad and clear-cut policy of the Act concluded that it sets a "high standard" for federal agencies, that there is no "escape hatch for footdragging agencies," that the Act does not make the preparation and use of these impact statements "discretionary," that Congress did not intend for this Act to be "a paper tiger." 346 F. Supp., at 199.[7]

---

[7] When Congress desires exceptions to be made to the impact statement requirement under the National Environmental Policy Act, express exemption is provided. For example, Pub. Law 92-307, 86 Stat. 191, provides that the Atomic Energy Commission can grant a temporary operating license for a nuclear power reactor without the completion of an environmental impact statement, if the application for the operating license was filed before September 9, 1971, and the Commission holds a hearing which leads to the findings, among others, that the operation of the facility during the period of the temporary operating license in accordance with its terms and conditions will provide adequate protection of the environment during the period of the temporary operating license and that the operation of the facility is essential toward insuring the power generating capacity of a utility system. The Commission is empowered to impose such terms and conditions as it deems necessary, and its decision is subject to judicial review.

Some federal agencies are taking affirmative action to promote the purposes of § 105. Thus the Securities and Exchange Commission recently adopted amendments to its registration and reporting forms to require more meaningful disclosure of certain items pertaining to the effect on the issuer's business of compliance with federal, state, and local laws and regulations relating to the protection of the environment. The amendments will require as a part of the description of the issuer's business, appropriate disclosures with respect to

*Arrow Transportation Co.* v. *Southern R. Co.*, 372 U. S. 658, does not preclude review here. In *Arrow* there were rates which the Commission had the power to suspend but had not done so. The power of suspension was entrusted to the Commission only; and we held that the courts should not intrude when the Commision has not acted. Here the Commission has acted; it has found that "the increases here proposed are just and reasonable, that the revenues derived therefrom will result in earnings and rates of return . . . not in excess of that required to enable" the carriers "to render adequate and efficient transportation at the lowest cost consistent with the furnishing of such service." I. C. C., at —. The Commission said it was not prescribing rates, though it attached conditions on approval of the rates without suspension. *Id.*, at —. It made clear it would suspend the new rates if the conditions were not added. As stated by the three-judge court "A suspension doctrine which effectively blackmails the carriers into submitting agency-authored rates is functionally indistinguishable from an order setting those rates." 346 F. Supp., at 197.

Moreover, as the three-judge court held and as Judge Friendly observed in *New York* v. *United States*, 337 F. Supp. 150, 164, "NEPA is a new and unusual statute imposing substantive duties which overlie those imposed on an agency by the statute or statutes for which it has jurisdictional responsibility."

---

the material effects which compliance with environmental laws and regulations may have upon the capital expenditures, earnings and competitive position of the issuer and its subsidiaries. Other amendments describe the extent to which litigation disclosures should contain specific descriptions of environmental proceedings. (Letter from the Securities and Exchange Commission, Ronald Hunt, Secretary, Amend. effective July 3, 1973.) See *Scientists' Institute* v. *AEC*, — F. 2d —, decided June 12, 1973, holding that an impact statement must be filed for the Commission's liquid metal fast breeder reactor program.

The Court today greatly weakens NEPA in a crucially important segment of the federal environmental field. Movement of litter to recycling plants[8] is critically important, as Chairman Train makes abundantly clear. The alternative is to leave it underfoot or to cart if off as garbage to incinerators that pollute the air or to landfills that are getting more and more difficult to find.[9] We know that recycled paper, recycled copper, recycled iron, recycled glass is practical. The Federal Bureau of Mines in its pilot plant at Edmonston, Maryland, boasts that "urban ore," as it calls this debris, costs about $3 a ton and recycled is worth $11 a ton. We know that we deal here with nonrenewable resources. We are told that recycling paper saves thousands of acres of trees a year.[10]

---

[8] Senator Jackson recently was reported as saying about these impact statements:

"We should also be able to get generic environmental impact statements—updated every six months or so—for energy policy, transportation policy, and other major policy decisions." *Supra*, n. 2, at —.

[9] Most of the Nation's waste is relocated into dumps with only approximately 10 to 15% finding its way into sanitary landfills. Science and Public Affairs, Energy Conservation and Waste Recycling, April 1973, p. 13, 17.

[10] Congressman Dingell, another main sponsor of NEPA recently was reported as saying:

"The success of the environmental impact statements is not so much that they were used as we intended they should, but that citizens have been able to use the process as a way to get into courts. . . . Some agencies are complying poorly. They decide what they are going to do and then write an environmental impact statement to support the decision. That is not what Congress had in mind. I am fearful that we are breeding a race of impact statement writers who put all the right words down but don't really get environmental concerns involved in the decision-making process. The impact statement itself is not important. The important thing is that proper judgments are made reflecting environmental considerations in the decision-making process. The impact statement should be

Under the Act, the appraisal by the Council on Environmental Quality of which Russell Train is the chairman is a weighty one for under § 201 of the Act it has the responsibility "to appraise programs and activities of the Federal Government" in light of the policy of the Act and "to formulate and recommend national policies to promote the improvement of the quality of the environment." C. E. Q. is, in other words, the expert *ombudsman* in the environmental area.

The apparent tendency among federal agencies, Congressman Dingell says,[11] is to decide first what they want to do and then prepare an impact statement as an *apologia* for what they have done. That puts the cart before the horse. That is what the Commission did here. But that is to adopt "an excessively narrow construction" of its statutory power "to avoid compliance" with the new environmental standards—all as condemned in the Conference Report, *supra,* at 2770. That is to say, environmental considerations are, so far as possible, to shape all agency policies and decisions.

These cases are, indeed, Exhibit A of the current practice of federal agencies to undermine the policy announced by Congress in NEPA. Rail rates were long discriminatory in retarding the industrial development of the South. *New York* v. *United States,* 331 U. S. 284. The present rates are arguably discriminatory against the removal of the litter which is about to engulf us. The wisdom of Chairman Train, rather than the technical maneuvers of the Commission, should be our guide.

I would affirm the judgment of the District Court.

---

a discipline for this and also a process by which the public can be informed and brought into the decision-making process." *Supra,* n. 2, at —.

For a recent account of impact statements on transportation problems see Robert Cahn (former member of CEQ), Christian Science Monitor, Feb. 28, 1973, p. 12.

[11] See n. 10, *supra.*

# APPENDIX I

The Bureau of Mines had at Edmonston, Maryland, for several years an incinerator residue processing plant on the basis of which Lowell, Massachusetts, instituted its Resource Recovery Project.

The Edmonston project is now engaged in recycling of raw waste and the following is the Bureau's description of the nature and scope of that project.

## FACT SHEET

Edmonston (Md.) Solid Waste Recycling Project
Bureau of Mines

DEPARTMENT OF THE INTERIOR

An important part of the solid waste utilization research carried on by the Bureau of Mines is to develop methods and processes for recycling mineral materials present in urban refuse. Engineers from the Bureau's College Park (Md.) Metallurgy Research Center operate a pilot plant at Edmonston, Maryland, where they reclaim ferrous metals, nonferrous metals, glass, plastics, and paper from raw unburned refuse. The following facts are pertinent to the research underway at the Edmonston pilot plant.

xxx—100 pounds of typical municipal refuse contains:
36.6 pounds of paper and cardboard; 20.2 pounds of garbage; 8.4 pounds of metal; 8.5 pounds of glass; 17.4 pounds of leaves, grass, hedge clippings and tree prunings; 2.6 pounds of scrap wood; 1.1 pound of plastics; and 5.2 pounds of miscellaneous material including leather, rubber, textiles, bricks, stones, and dirt.

xxx—Urban refuse generated in the U. S. in 1972 totaled 300 million tons, or the equivalent of more than 8 pounds daily for every man, woman, and child.

xxx—Only 220 million tons of municipal refuse was regularly collected by public agencies and private firms. The remainder (80 million tons) was abandoned, dumped at the point of origin, or hauled to uncontrolled disposal sites.

xxx—The volume of municipal refuse accumulating in the U. S. in a single year would cover an area half the size of the State of

Connecticut (2,500 sq. mi.) with a layer of refuse 1 foot deep. This refuse contains some 12 million tons of iron and steel, 13 million tons of glass, and over a million tons of aluminum, zinc, lead, tin, and copper.

xxx—Collecting and disposing of refuse costs cities an average of \$23 per ton (\$18, for collection and \$5, for disposal). New York City, at a cost of \$40 per ton, spends almost a million dollars each day to collect and dispose of solid waste. Total U. S. bill runs about \$6 billion annually.

xxx—Most municipal refuse is disposed of by dumping, landfill, or incineration. About 30 million tons of municipal refuse is burned annually in more than 300 municipal incinerators. These incinerators generate 7.5 million tons of residues, which are then buried. The process developed by the Bureau to reclaim the values from incinerator residues has attracted world-wide attention. A commercial size plant of this type will soon be under construction in Lowell, Massachusetts, with seventy-five percent of the \$3.2 million required, being provided by the Environmental Protection Agency.

xxx—Successful reclamation of mineral values from incinerator residues at the Bureau's pilot plant prompted research to save also that part of municipal refuse that is now being lost during burning. This would reduce the need for building more municipal incinerators, saving their construction and operating costs, and would bring income from salvaged paper and plastics as well as metals and glass. It would also eliminate air pollution problems connected with incineration.

xxx—Equipment for mechanical separation of metals, glass, paper, and plastics from municipal refuse before incineration has been assembled at Edmonston. The process involves coarse shredding of the refuse, followed with air classification, magnetic separation, screening, optical sorting, electrostatic separation, and gravity concentration—all proven methods used in the mineral industries.

xxx—Other refuse recycling schemes have been proposed and some are already under development. The process developed by the Bureau is unique in the following major respects: (1) It is the only process that embodies a complete system, (2) it is the only process capable of capturing and concentrating putrescibles and glass, (3) it is the only process that produces a tin product suitable for detinning, (4) it is the only process capable of accepting extremely massive pieces of metal, (5) it is the only

process that can successfully separate plastics and paper, and (6) energy requirements for the Bureau's process are by far the least of all proposed processes.

xxx—A plant processing 1,000 tons of raw refuse per day could be expected to reclaim each day enough ferrous metal to make all the iron and steel parts for more than 55 4-door sedans.

xxx—About 36 billion bottles are discarded each year in the U. S. as solid waste. Each American discards a glass bottle on the average of about one every two days. The average returnable beer bottle used to make 31 round trips from the brewery, to the consumer, and back to the brewery. The average is now 19 trips. In some cities, it is only 4. People are discriminating less between returnable and non-returnable bottles.

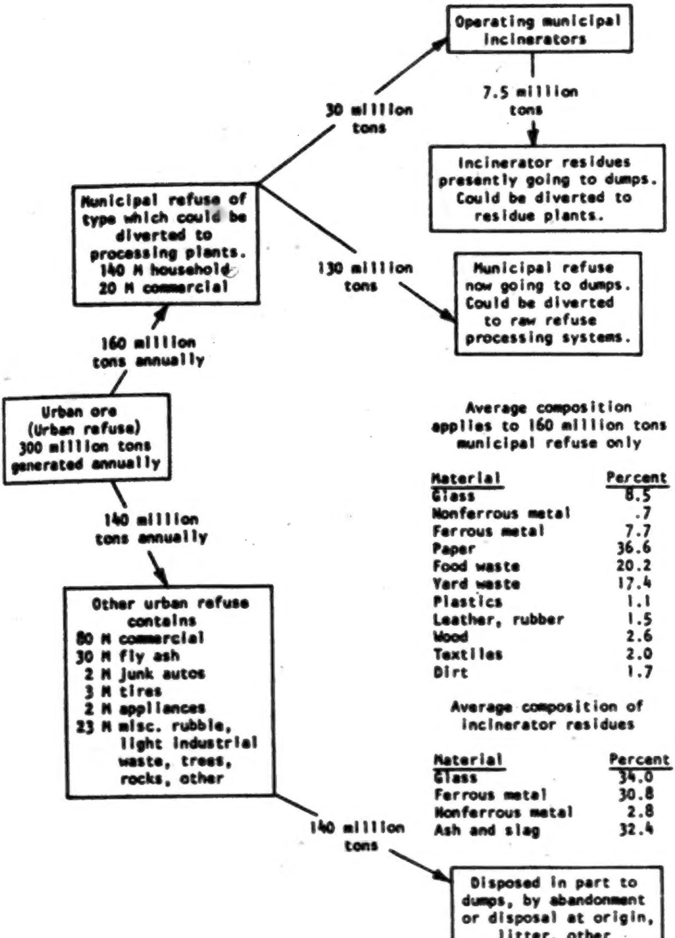
xxx—Glass reclaimed from raw refuse can be used in making new glass, or for such salable products as building bricks, mineral wool for insulation, and road surfacing (when ground and mixed with asphalt).

xxx—Aluminum present in refuse in the form of cans alone amounts to 10 percent of the total primary production. This metal together with other aluminum recovered from refuse would find a ready market at existing secondary smelters for conversion to high grade casting alloys.

xxx—The other heavy nonferrous metals could be used readily in producing brass ingot or the mixture could be further refined and separated into the constituent metals.

xxx—The rate at which we generate refuse is growing so fast that within 20 years, even if we are able to recycle 70 percent of our solid wastes our needs for landfill space will remain the same. And landfill space is, even now, becoming harder and harder to find.

URBAN REFUSE DISPOSAL IN THE UNITED STATES 1972



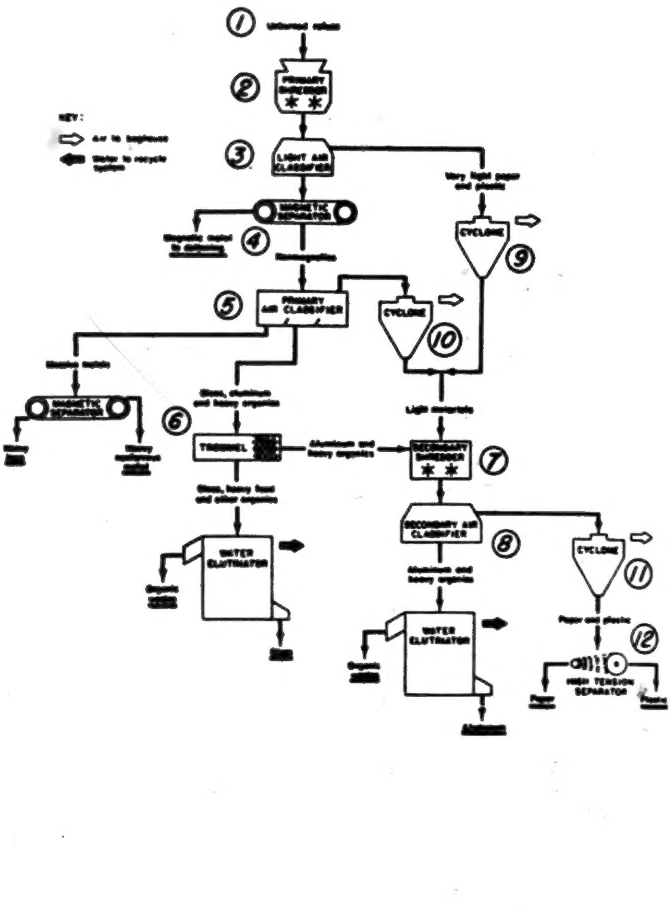

Average composition applies to 160 million tons municipal refuse only

| Material | Percent |
|---|---|
| Glass | 8.5 |
| Nonferrous metal | .7 |
| Ferrous metal | 7.7 |
| Paper | 36.6 |
| Food waste | 20.2 |
| Yard waste | 17.4 |
| Plastics | 1.1 |
| Leather, rubber | 1.5 |
| Wood | 2.6 |
| Textiles | 2.0 |
| Dirt | 1.7 |

Average composition of incinerator residues

| Material | Percent |
|---|---|
| Glass | 34.0 |
| Ferrous metal | 30.8 |
| Nonferrous metal | 2.8 |
| Ash and slag | 32.4 |

BUREAU OF MINES DRYSORT REFUSE RECOVERY SYSTEM



## APPENDIX II

Section 102 of the Environmental Protection Act, 42 U. S. C. § 4332 provides:

§ *4332. Cooperation of agencies; reports; availability of information; recommendations; international and national coordination of efforts*

The Congress authorizes and directs that, to the fullest extent possible: (1) the policies, regulations, and public laws of the United States shall be interpreted and administered in accordance with the policies set forth in this chapter, and (2) all agencies of the Federal Government shall—

(A) utilize a systematic, interdisciplinary approach which will insure the integrated use of the natural and social sciences and the environmental design arts in planning and in decisionmaking which may have a impact on man's environment;

(B) identify and develop methods and procedures, in consultation with the Council on Environmental Quality established by subchapter II of this chapter, which will insure that presently unquantified environmental amenities and values may be given appropriate consideration in decisionmaking along with economic and technical considerations;

(C) include in every recommendation or report on proposals for legislation and other major Federal actions significantly affecting the quality of the human environment, a detailed statement by the responsible official on—

(i) the environmental impact of the proposed action,

(ii) any adverse environmental effects which cannot be avoided should the proposal be implemented,

(iii) alternatives to the proposed action,

(iv) the relationship between local short-term uses of man's environment and the maintenance and enhancement of long-term productivity, and

(v) any irreversible and irretrievable commitments of resources which would be involved in the proposed action should it be implemented.

Prior to making any detailed statement, the responsible Federal official shall consult with and obtain the comments of any Federal agency which has jurisdiction by law or special expertise with respect to any environmental impact involved. Copies of such statement and the comments and views of the appropriate Federal, State, and local agencies, which are authorized to develop and enforce environmental standards, shall be made available to the President, the Council on Environmental Quality and to the public as provided by section 552 of Title 5, and shall accompany the proposal through the existing agency review processes;

(D) study, develop, and describe appropriate alternatives to recommended courses of action in any proposal which involves unresolved conflicts concerning alternative uses of available resources;

(E) recognize the worldwide and long-range character of environmental problems and, where consistent with the foreign policy of the United States, lend appropriate support to initiatives, resolutions, and programs designed to maximize international cooperation in anticipating and preventing a decline in the quality of mankind's world environment;

(F) make available to States, counties, municipalities, institutions, and individuals, advice and in-

formation useful in restoring, maintaining, and enhancing the quality of the environment;

(G) initiate and utilize ecological information in the planning and development of resource-oriented projects; and

(H) assist the Council on Environmental Quality established by subchapter II of this chapter.

Pub. L. 91–190, Title I, § 102, Jan. 1, 1970, 83 Stat. 853.

# SUPREME COURT OF THE UNITED STATES

Nos. 72–535 AND 72–562

| | |
|---|---|
| United States and Interstate Commerce Commission, Appellants, 72–535 *v.* Students Challenging Regulatory Agency Procedures (SCRAP) et al. | On Appeals from the United States District Court for the District of Columbia. |
| Aberdeen and Rockfish Railroad Company et al., Appellants, 72–562 *v.* Students Challenging Regulatory Agency Procedures (SCRAP) et al. | |

[June 18, 1973]

MR. JUSTICE WHITE, with whom THE CHIEF JUSTICE and MR. JUSTICE REHNQUIST join, dissenting in part.

I would reverse the judgment of the District Court and order the complaint dismissed because appellees lack standing to bring this suit. None of our cases, including inferences that may be drawn from dicta in *Sierra Club* v. *Morton,* where we denied standing to petitioner there, are sufficient to confer standing on plaintiffs in circumstances like these. The allegations here do not satisfy the threshold requirement of injury in fact for constituting a justiciable case or controversy. The inquiry alleged is that the failure of the Commission to suspend a 2.5% freight rate increase may discourage the transportation of recyclable materials, thus retarding the use of recycled materials, causing further consumption of our forests and natural resources (some

of which might be taken from the Washington Metropolitan area), and resulting in more refuse and undisposable materials to further pollute the environment.

The majority acknowledges that these allegations reflect an "attentuated line of causation," *ante,* p. —, but is willing to suspend its judgment in the dim hope that proof at trial will in some unexplained way flesh them out and establish the necessary nexus between these plaintiffs and the across-the-board rate increase they complain of. To me, the alleged injuries are so remote, speculative and insubstantial in fact that they fail to confer standing. They become no more concrete, real or substantial when it is added that materials will cost more at the marketplace and that somehow the freight rate increase would increase air pollution. Allegations such as these are no more substantial and direct and no more qualify these plaintiffs to litigate than allegations of a taxpayer that governmental expenditures will increase his taxes and have an impact on his pocketbook, *Massachusetts* v. *Mellon,* 262 U. S. 447, 486–489 (1923), or allegations that governmental decisions are offensive to reason or morals. The general "right, possessed by every citizen, to require that the Government be administered according to law and that public monies not be wasted" does not confer standing to litigate in federal courts. *Fairchild* v. *Hughes,* 258 U. S. 126, 129 (1922). New York did not have standing to complain when it asserted merely the possible adverse effects of diversion of water from Lake Michigan upon hypothetical power developments in "the indefinite future." *New York* v. *Illinois,* 274 U. S. 488, 490 (1927). Assumed potential invasions are insufficient basis for a justiciable case and controversy. *Arizona* v. *California,* 283 U. S. 423, 462 (1931). As I see the allegations in this case, they are in reality little different from the general interest allegations found insufficient and too remote in

*Sierra Club.* If they are sufficient here, we are well on our way to permitting citizens at large to litigate any decisions of the Government which fall in an area of interest to them and with which they disagree.

Assuming, however, that a majority of the Court adheres to the conclusion that a constitutional case or controversy exists in these circumstances and that plaintiffs may sue, I would agree that the District Court erred in entering an injunction which Congress quite clearly had long since divested it of the power to enter. Accordingly, I join Part III of the Court's opinion. I add only that failure to maintain this country's railroads even in their present anemic condition will guarantee that recyclable materials will stay where they are—far beyond the reach of recycling plants that as a consequence may not be built at all.

# SUPREME COURT OF THE UNITED STATES

Nos. 72-535 AND 72-562

United States and Interstate Commerce Commission, Appellants,
72-535 v.
Students Challenging Regulatory Agency Procedures (SCRAP) et al.

Aberdeen and Rockfish Railroad Company et al., Appellants,
72-562 v.
Students Challenging Regulatory Agency Procedures (SCRAP) et al.

On Appeals from the United States District Court for the District of Columbia.

[June 18, 1973]

MR. JUSTICE MARSHALL, concurring in part and dissenting in part.

I fully agree with and join in Part II of the Court's opinion wherein it sustains the District Court's determination that the appellees have standing to challenge the 2.5% interim surcharge on the ground that the Interstate Commerce Commission's order of April 24 permitting the surcharge to take effect was not issued in compliance with the requirements of the National Environmental Policy Act of 1969 (NEPA), 42 U. S. C. §§ 4321-4347. The Court goes on, however, to hold in Part III of its opinion that the District Court lacked power to issue a preliminary injunction barring implementation of the surcharge due to the Commission's alleged failure to comply with NEPA in the suspension

stage of the rate proceeding. The Court's decision in this respect is, to be sure, a very narrow one; the decision clearly concerns only the scope of remedies available to the District Court in the context of a case of this particular character,[1] that is, an ICC rate suspension case. The Court specifically refrains from deciding whether or not the Commission's alleged failure to comply with NEPA in the suspension stage is a proper subject for judicial review, and if so, what would constitute adequate compliance with NEPA at that juncture in the administrative process. See *ante,* at 27 n. 22. Nonetheless, I am unable to join the third portion of the Court's opinion, for I am convinced that there is no lack of judicial power to issue a preliminary injunction against the interim surcharge in the context of this case. I therefore must respectfully dissent from Part III of the Court's opinion.

At the outset, it is essential for purposes of analysis to put the issue upon which the Court disposes of the case in proper perspective. Since the Court addresses only the issue of the District Court's power to grant preliminary relief, we must, of course, assume for the sake of argument that the issues which the Court does not now reach—namely, whether the procedural requirements of NEPA[2] are applicable at the suspension stage and

[1] Given that the Court holds only that the District Court lacked power to grant preliminary injunctive relief, it presumably remains open to appellees to challenge the Commission's alleged failure to comply with NEPA in the suspension stage of the proceedings concerning the interim surcharge in an action for declaratory relief. Nor does anything in the Court's opinion today deny to the District Courts power to enjoin the Commission to comply with NEPA in the context of a particular rate proceeding so long as no injunction is issued barring implementation of the rates themselves, cf. *Atchison, T. & S. F. R. Co.* v. *Wichita Board of Trade, ante,* p. —.

[2] See in particular § 102 (2)(C) of the Act, 42 U. S. C. § 4332 (2)(C).

whether the issue of Commission compliance is a proper one for judicial review [3]—are to be decided in appellees' favor. In addition, we must accept for the present appellees' assertions that the interim surcharge, by raising the cost of shipping recyclable materials, will further accentuate the allegedly unjustifiable disparity between the cost of shipping those materials and the cost of shipping primary goods, thereby irrationally encouraging the use of primary goods which will lead to a further degradation of our environment. In other words, in considering the question of judicial power, we must accept the correctness of the District Court's determination that there was a "strong likelihood" that the Commission had erred in its conclusion that the interim surcharge "'will have no significant adverse effect on . . . the quality of the human environment within the meaning of the Environmental Policy Act of 1969,'" 346 F. Supp., at 200, 201, a conclusion that had effectively excused the Commission from compliance with the procedural requirements of NEPA in the context of the surcharge, see 42 U. S. C. § 4332 (2)(C).

Turning then to the issue of judicial power, it must first be recalled that we deal here with the grant of only a preliminary injunction; the District Court did not permanently enjoin enforcement of the interim surcharge upon determining that the Commission had, in all likelihood, failed to comply with NEPA in the suspension stage. Properly viewed, I think the injunction at issue in this case amounts to nothing more than a legitimate effort by the District Court, following the Commission's refusal to suspend the surcharge, to maintain the *status*

---

[3] Cf., *e. g., Upper Pecos Assn.* v. *Stans,* 452 F. 2d 1233 (CA10 1971), vacated and remanded for consideration of mootness *sub nom. Upper Pecos Assn.* v. *Peterson,* 409 U. S. 1021 (1972); *Calvert Cliffs' Coordinating Comm'n* v. *United States AEC,* — U. S. App. D. C. —, 449 F. 2d 1109 (1971); *City of New York* v. *United States,* 337 F. Supp. 150, 158–160 (EDNY 1971).

*quo* pending final judicial determination of the legality of the Commission's action at the suspension stage in light of the requirements of NEPA. And, by now, the equitable power of the federal courts to grant interim injunctive relief pending determination of an appeal is well established. The nature of that power was explored at length by the Court in *Scripps-Howard Radio, Inc.* v. *FCC,* 316 U. S. 4 (1942), where it was held that a court of appeals had power, pending determination of an appeal, to stay the Federal Communications Commission's grant of a construction permit although the Federal Communications Act made no provision for such a stay. Speaking for the Court, Mr. Justice Frankfurter explained:

> "No court can make time stand still. The circumstances surrounding a controversy may change irrevocably during the pendency of an appeal, despite anything a court can do. But within these limits it is reasonable that an appellate court should be able to prevent irreparable injury to the parties or to the public resulting from premature enforcement of a determination which may later be found to have been wrong. It has always been held, therefore, that as a part of its traditional equipment for the administration of justice, a federal court can stay the enforcement of a judgment pending the outcome of an appeal." *Id.*, at 9–10. See also *FTC* v. *Dean Foods Co.,* 384 U. S. 597, 604 (1966); *Whitney National Bank in Jefferson Parish* v. *Bank of New Orleans & Trust Co.,* 379 U. S. 411, 425 (1965).

This Court has consistently adhered to the view that it will find federal courts to have been deprived of their traditional power to stay orders under review only in the face of the clearest possible evidence of a congressional intent to do so. See *Scripps-Howard Radio, Inc.* v. *FCC,* 316 U. S., at 11, 15. No such clear intent is to

be found in the Interstate Commerce Act, at least not with respect to a case such as this where the Commission has already acted on the relevant issue and the issue lies in an area outside the Commission's traditional expertise.[4] In *Arrow Transportation Co.* v. *Southern Railway Co.*, 372 U. S. 658, 664 (1963), this Court specifically acknowledged that "[i]t cannot be said that the legislative history of the grant of suspension power to the Commission includes unambiguous evidence of a design to extinguish whatever judicial power may have existed prior to [the establishment of suspension powers in the Commission] to suspend proposed rates." The *Arrow* Court was asked to extend by injunction the statutory seven-month suspension period, see 49 U. S. C. § 15 (7), because the Commission had not reached a decision on the lawfulness of the proposed rates at the end of the suspension period and the rail carriers, following a period of voluntary suspension, were threatening to implement the rate change without awaiting final agency action. Despite the ambiguity of the legislative history, the Court, upon careful examination of the character of and reasons for the suspension scheme, concluded that Congress must have intended to deprive the federal courts of the power to suspend rates pending completion of agency action and thus that the traditional equitable powers of the federal courts had been overriden to that extent. But as detailed consideration of the factors that motivated the decision in *Arrow* reveals, this case presents a significantly different problem.

---

[4] Thus, I cannot accept the Court's assertion that the question in this case is "whether in a specific context NEPA *sub silentio* revived judicial power that had been explicitly eliminated by Congress." *Ante*, at 24. That is a question which I do not believe need ever be reached here, for—as shall be seen—Congress has not, to begin with, deprived the federal courts of their traditional equitable powers in the context of this case.

The *Arrow* Court felt that an injunction extending the suspension period pending final agency action would involve a serious, unintended intrusion on the primary jurisdiction of the Commission. This problem of primary jurisdiction had two aspects in *Arrow*. First, where the issue is the reasonableness of proposed rates, an application for an injunction against implementation of those rates pending final agency action would necessarily require a federal court "to pass before final Commission action upon the question of reasonableness of a rate," 372 U. S., at 671, thereby providing, in effect, an advisory judicial opinion to the Commission on an issue which Congress intended that the Commission decide in the first instance. Certainly, the Commission's expertise in matters of rail carrier operations and economics is well recognized, and *Arrow* clearly indicates that the courts should not interfere with the exercise of that expertise. However, the grant of preliminary relief in this case involves no such interference with the Commission's inital exercise of its particular expertise.

So far as I am aware, the Commission has never been deemed especially expert in matters of environmental policy or impact.[5] It is, of course, true that the Commission must decide in the first instance whether particular proposed action constitutes "major Federal action significantly affecting the quality of the human environment," thus necessitating agency compliance with the detailed requirements of § 102 (2)(C) of NEPA, 42 U. S. C. § 4332 (2)(C). But that decision had already been made in this case *prior to* the time when judicial intervention by the District Court was sought—in contrast to the situation in *Arrow* where the question of the reasonableness of the rates remained unresolved by the

---

[5] Administrative expertise in such matters is surely lodged with the Environmental Protection Agency and the Council on Environmental Quality.

Commission. Even assuming that some element of agency expertise is involved in the decision at issue here, the District Court, in granting preliminary relief against the interim surcharge, passed only upon a question of which the Commission had finally disposed, namely, the environmental impact of not suspending the interim surcharge and of permitting it to take effect at once. Thus, for purposes of the particular issue raised in this case, the District Court was presented with final agency action [6] and was not in danger of interfering with the Commission's expertise when it stayed the Commission's order pending final determination of the appeal.[7]

The other aspect of the problem of primary jurisdiction focused upon in *Arrow* was the timing of the implementation of new rates. The Court concluded that Congress had intended that the Commission should determine when new rates should take effect. See 372 U. S., at 668. Insofar as the economic impact of rate increases was concerned, Congress enacted a scheme which permitted the Commission to take into account the interests of both rail carriers and shippers. Thus, Congress recognized that economic necessity might persuade the Commission to permit otherwise questionable rates to go unsuspended while they were being investigated, and, at most, it allowed the Commission to suspend proposed rates for only seven months, see 49 U. S. C. § 15 (7). At the same time, Congress attempted to accommodate the economic interests of shippers, for it gave the Commission power, pending final agency action, to require the rail carriers to maintain detailed records of monies received due to the increase and to compel payment of

---

[6] Cf. L. Jaffe, Judicial Control of Administrative Action 688 (1965).

[7] Contrast *Atchison, T. & S. F. R. Co.* v. *Wichita Board of Trade, ante,* p. —.

refunds if a rate increase was ultimately found to be unreasonable.[8] See *ibid.*

But where does the Interstate Commerce Act make provision for an accounting and "refund" to the people of our Nation for the irreversible ecological damage that results from a rate increase which discriminates unreasonably against recyclable materials and has been allowed to take effect without compliance with the procedural requirements of NEPA?[9] The Court today says that

---

[8] Moreover, even if the Commission fails to require record keeping and the payment of refunds *sua sponte*, Congress also provided a mechanism by which shippers may initiate an action before the Commission to seek reparations from a carrier on the ground that particular rates are unreasonable. See 49 U. S. C. § 13 (1).

*Arrow*, to be sure, did not involve an economic dispute between shippers and rail carriers, but was, instead, an action brought by water carriers who contended that certain challenged decreases in the rates of competing rail carriers were designed to destroy them rather than the result of legitimate economic considerations. Obviously, the refund and reparation provisions of the Interstate Commerce Act were of no more value to the water carriers in *Arrow* than they are to the nonshipper appellees in this case. But, as the Court pointed out in *Arrow*, "[c]onflicts over rates between competing carriers were familiar to the Commission long before [the enactment of the suspension provisions] . . . . Indeed, in another provision of the very same statute [that established the suspension powers] Congress . . . dealt explicitly with *reduction* of rates by railroads competing with water carriers [—namely, 49 U. S. C. §4 (2)]. In addition § 8 of the Act, 49 U. S. C. § 8, creates a private right of action for damages—based on conduct violative of the Act—which might be available . . . ." 372 U. S., at 669. Thus, Congress had taken into account, and had provided for, disputes between competing carriers, as well as between shippers and carriers, in enacting the suspension provisions. The same can hardly be said for conflicts between the environmental policies of NEPA and the Commission's suspension power.

[9] Indeed, given the substantial element of public interest at stake in a case such as this, it is appropriate to recall Justice Stone's oft-quoted admonition: "Courts of equity may, and frequently do, go much further both to give and withhold relief in furtherance of the

"[t]o allow judicial suspension for noncompliance with NEPA, would disturb the careful balance of interests" struck by Congress in the suspension and refund provisions. *Ante*, at 25–26. Yet the simple fact is that in the carefully designed suspension and refund scheme no balance was struck with respect to the environmental interests that have been recognized by Congress in NEPA *since* the introduction of the suspension provisions into the Interstate Commerce Act. Under these circumstances, we can hardly infer an intent on the part of Congress to deprive the federal courts of their traditional responsibility, in passing upon a request for equitable relief, to work an accommodation in each particular case of the competing interests of the relevant parties [10]—that is, of a rail carrier's alleged need for increased income that will otherwise be forever lost each day that the new rate is not changed and of the extent of irreversible environmental damage that might result if the rates are not suspended. The District Court, in its effort to preserve the *status quo* pending final review of the Commission's April 24 order, gave full consideration to the effects on all parties of either granting or denying preliminary relief against the interim surcharge.[11] In then temporarily enjoining the surcharge, I believe that the District Court acted within the scope of its legitimate powers.

To summarize, then, I obviously cannot agree with the Court's assertion that "each of the policies that we

---

public interest than they are accustomed to go when only private interests are involved." *Virginia R. Co.* v. *Systems Federation No. 40*, 300 U. S. 515, 552 (1937).

[10] Cf. *Hecht Co.* v. *Bowles*, 321 U. S. 321, 329–330 (1944).

[11] Thus, the District Court, fully recognizing the financial plight of the rail carriers, carefully limited its preliminary injunction to the application of the interim surcharge to recyclable materials, "allowing [the rail carriers] to collect the surcharge on all nonrecyclable goods." 346 F. Supp., at 202.

identified in *Arrow* as the basis for § 15 (7) would be substantially undermined if the courts were found to have suspension powers simply because noncompliance with NEPA was alleged." *Ante*, at 25. In *Arrow* itself, the Court was at pains to point out that its decision did not "reflect in any way upon decisions which have recognized a limited judicial power to preserve the court's jurisdiction or maintain the *status quo* by injunction pending review of an agency's action through prescribed statutory channels." 372 U. S., at 671 n. 22. True, the Court went on to say there that "[s]uch power . . . has never been recognized in derogation of such a clear congressional purpose to oust judicial power as that manifested in the Interstate Commerce Act." *Ibid.* But the import of that remark must be judged with a full understanding of the factors underlying the *Arrow* Court's find of "such a clear congressional purpose." As has been seen, close analysis of those factors identified certainly does not compel extension of the *Arrow* holding to the request for preliminary injunctive relief in this case.[12] The Court would do well to re-

---

[12] The *Arrow* Court also pointed out that experience with judicial injunctions against rates prior to the establishment of the Commission's suspension powers in § 15 (7) had "resulted in disparity of treatment as between different shippers, carriers, and sections of the country, causing in turn 'discrimination and hardship to the general public.'" 372 U. S., at 664. These results were due both to the conflicting views of lower federal courts as to their power to enjoin rates pending agency determination of their lawfulness and conflicting judgments of different courts as to the reasonableness of the same rates. See. *id.*, at 663–664. But the danger of conflicting judgments concerning the same rates and unevenhanded treatment of shippers and carriers, merely because of the fortuity of the particular judicial district in which they are located, is not present where, as here, the allegation is that the Commission has failed to follow the requirements of a statute—NEPA—relevant to the exercise of its regulatory jurisdiction and the Commission has, as a consequence, been joined in the suit as a defendant. So long as the Commission has been

member that "[w]here Congress wished to deprive the courts of [their] historic powers [to enjoin orders pending review], it knew how to use apt words . . . ." *Scripps-Howard Radio, Inc.* v. *FCC,* 316 U. S., at 17. Cf. *Hecht Co.* v. *Bowles,* 321 U. S. 321, 329 (1944). Nothing in the language of the Interstate Commerce Act or in the particular structure of that Act or even in our decision in *Arrow* compels the conclusion that Congress has done so here. I must therefore dissent from the Court's ultimate disposition of this case.

---

made a party, it is possible to ensure uniformity of treatment by enjoining the Commission to exercise its suspension powers where a failure to comply with NEPA is believed to exist. This is what the District Court did here when it enjoined the Commission "from permitting . . . the 2.5 percent surcharge" to be collected by the rail carriers "pending further order of this court." See Jurisdictional Statement, at 30a. It may be that the danger of conflicting results where the Commission has not been made a party would warrant a court staying its hand, but that is not a problem in this case.

NOTE: Where it is feasible, a syllabus (headnote) will be released, as is being done in connection with this case, at the time the opinion is issued. The syllabus constitutes no part of the opinion of the Court but has been prepared by the Reporter of Decisions for the convenience of the reader. See *United States* v. *Detroit Lumber Co.*, 200 U.S. 321, 337.

# SUPREME COURT OF THE UNITED STATES

## Syllabus

## WEINBERGER ET AL. *v.* BENTEX PHARMACEUTICALS, INC., ET AL.

CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

No. 72-555. Argued April 17, 1973—Decided June 18, 1973

Respondent drug marketers filed suit for a declaratory judgment that their drugs containing pentylenetetrazol are generally recognized as safe and effective and thus are not "new drugs" within the meaning of § 201 (p) of the Federal Food, Drug. and Cosmetic Act of 1938, as amended. They also sought exemption under § 107 (c)(4), the grandfather clause, of the 1962 amendments to the Act. The Food and Drug Administration (FDA) Commissioner, based on NAS-NRC panel reports, concluded that there was a lack of substantial evidence that the drugs were effective for their intended uses and gave notice of his intention to initiate proceedings to withdraw approval of the new drug applications (NDA's). In light of the FDA's position that withdrawal of approval of an NDA would operate to remove marketing approval for all drugs of similar composition, known as "me-too" drugs, whether or not expressly covered by an effective NDA, the Commissioner invited holders of NDA's for drugs containing pentylenetetrazol "and any interested person who might be adversely affected by their removal from the market" to submit "adequate and well-controlled studies" to establish the effectiveness of the drugs. Only one NDA holder submitted further evidence, which the Commissioner held did not satisfy the statutory standard. He gave notice of intent to issue an order withdrawing approval of the NDA's, and only one NDA holder requested a hearing but filed no supporting data. The Commissioner issued orders withdrawing approval of the NDA's and no appeal was taken. Respondents here all market "me-too" drugs, none of which was expressly covered by an effective NDA. The District Court held that the FDA should resolve the "new drug" and "grandfather" issues in an administrative proceeding. The Court of Appeals

Syllabus

reversed and remanded with directions to the District Court to determine whether the challenged drugs may lawfully be marketed without approved NDA's, holding that the FDA has no jurisdiction, primary or concurrent, to decide what is a "new drug" for which an NDA is required.

*Held:* The District Court's referral of the "new drug" and "grandfather" issues to the FDA was proper. Pp. 3-9.

(a) While an FDA order denying an NDA and withdrawing one is reviewable by the Court of Appeals under § 505 (h), an order declaring a "new drug" status under § 201 (p) is reviewable under the Administrative Procedure Act by the District Court. Pp. 5-6.

(b) The reach of scientific inquiry under both § 505 (d) and § 201 (p) is the same, *Weinberger* v. *Hynson, Westcott & Dunning, Inc., ante*, p. —, and it is implicit in the regulatory scheme that the FDA has jurisdiction to decide with administrative finality, subject to judicial review, the "new drug" status of individual drugs or classes of drugs. Pp. 6-7.

(c) The "new drug" and "grandfather" issues are peculiarly suited to initial determination by the FDA with its specialized competence and expertise. Pp. 8-9.

463 F. 2d 363, reversed.

DOUGLAS, J., delivered the opinion of the Court, in which all Members joined, except BRENNAN, J., who took no part in the consideration or decision of the case, and STEWART, J., who took no part in the decision of the case.

NOTICE: This opinion is subject to formal revision before publication in the preliminary print of the United States Reports. Readers are requested to notify the Reporter of Decisions, Supreme Court of the United States, Washington, D.C. 20543, of any typographical or other formal errors, in order that corrections may be made before the preliminary print goes to press.

# SUPREME COURT OF THE UNITED STATES

No. 72–555

| | |
|---|---|
| Caspar W. Weinberger, Secretary of Health, Education, and Welfare, et al., Petitioners, *v.* Bentex Pharmaceuticals, Inc., et al. | On Writ of Certiorari to the United States Court of Appeals for the Fourth Circuit. |

[June 18, 1973]

MR. JUSTICE DOUGLAS delivered the opinion of the Court.

In this case Bentex and some 20 other firms that market drugs containing pentylenetetrazol filed this suit for a declaratory judgment that their drugs containing pentylenetetrazol are generally recognized as safe and effective and thus not "new drugs" within the meaning of § 201 (p)(1) of the Federal Food, Drug, and Cosmetic Act of 1938 as amended, 21 U. S. C. § 321 (p)(1). They also sought exemption from the new effectiveness requirements by reason of § 107 (c)(4) of the 1962 amendments to the Act, known as the "grandfather" clause.

As part of FDA's Drug Efficacy Study Implementation program, three separate NAS–NRC panels reviewed the evidence concerning these drugs, and each concluded that the drug was "ineffective" for the indicated use. The Commissioner concluded there was a lack of substantial evidence that these drugs were effective for their intended uses and gave notice announcing his intention to initiate proceedings to withdraw approval of the NDAs. FDA had taken the position that withdrawal of approval of an

NDA would operate to remove marketing approval for all drugs of similar composition, known as "me-too" drugs, whether or not they were expressly covered by an effective NDA.[1] Accordingly, the notice invited the holders of the NDAs for drugs containing pentylenetetrazol "and any interested person who might be adversely affected by their removal from the market" to submit "adequate and well-controlled studies" to establish the effectiveness of the drugs. See § 505 (d), 21 U. S. C. § 355 (d). Only one NDA holder submitted further evidence, which the Comissioner held did not satisfy the statutory standard. He thereupon gave notice of intent to issue an order withdrawing approval of the NDAs under § 505 (3), 21 U. S. C. § 355 (e). Again, all those who might be adversely affected by withdrawal of the NDAs were given the opportunity to participate. Only one NDA holder requested a hearing but filed no data to support it. The Commission issued orders withdrawing approval of the three NDAs (35 Fed. Reg. 14412); no appeal was taken. This suit in the District Court followed. It appears that all of the parties to this suit market "me-too" drugs, none of which was expressly covered by an effective NDA.

The District Court held that although it could determine whether the drugs were "new" or "grandfathered" drugs, its jurisdiction was concurrent with that of FDA

[1] 37 Fed. Reg. 23185–23187, adding § 130.40 to 21 CFR, defines "identical, related, or similar drug" as used in this Act to include "other brands, potencies, dosage forms, salts, and esters of the same drug moiety as well as of any drug moiety related in chemical structure or known pharmacological properties." It also provides all persons with an interest in such drugs an opportunity for hearing on any proposed withdrawal of NDA approval for the basic drug. A district court order, — F. Supp. —, directing FDA to apply the NAS–NRC evaluation to all "me-too" drugs is reproduced in 37 Fed. Reg. 26623–26624.

and that FDA should resolve the "new drug" issue in an administrative proceeding. — F. Supp. —. It entered an injunction to preserve the status quo and ruled that if FDA should decline to hold a hearing it would determine the issue. The Court of Appeals reversed and remanded with directions that the District Court determine whether the challenged drugs may lawfully be marketed without approved NDAs. — F. 2d —. It held that FDA has no jurisdiction, either primary or concurrent, to decide in an administrative proceeding what is a "new drug" for which an NDA is required. In its view the 1962 Act established two forums for the regulation of drugs: an administrative one for premarketing clearances for "new drugs" or withdrawal of previously approved NDAs with the right of appeal; and second, a judicial one for enforcement of the requirement that "new drugs" be cleared as safe and effective before marketing by providing the Government with judicial remedies of seizure, injunction and criminal prosecution available solely in the District Court. *Id.*, at —.

We reverse the Court of Appeals.

FDA, as a result of an NAS–NRC study and after due notice, faced up to the problem of proposing withdrawal on drugs found to be lacking in substantial evidence of effectiveness. One method would be to have 1,000 withdrawal hearings—perhaps as many as 3,500, each one lasting probably for weeks. The cost in time and budget would be enormous. Accordingly, FDA issued regulations,[2] already discussed in the *Hynson* cases, *ante,* defining the "scientific principles which characterize an adequate and well-controlled clinical investigation,"[3] which elaborates on the statutory "substantial evidence" test. And as we held in the *Hynson* cases, no basis for

[2] 35 Fed. Reg. 3073, 35 Feg. Reg. 7250.

[3] See the Appendix in the *Hynson* cases.

a hearing under these regulations would be laid unless a party seeking a hearing proffered at least some evidence of that nature and quality.

By May 1972, 102 final orders effecting withdrawal of approval for 452 NDAs had been issued; and they resulted in the removal from the market of an additional 1,473 "me-too" drugs.[4] FDA was still troubled because under the 1962 Act no census of the marketplace was authorized. That is why Congress enacted the Drug Listing Act of 1972, 86 Stat. 559, — U. S. C. —. That Act requires manufacturers to submit to FDA a list of all drugs they market, including data showing their composition, labeling, and advertising.[5] The Senate Report stated:[6]

> "The effective enforcement of the drug provisions of the Act requires the ready availability of a current inventory of all marketed drugs. The Secretary is just completing a thorough review of the effectiveness of drugs marketed pursuant to new drug applications during the period 1938–1962, as required by the Drug Amendments of 1962. Application of the results of this important review to related drugs would be frustrated if a list of all marketed drugs were not easily obtained."

FDA also realized that it is impossible to apply the 1962 amendments to over-the-counter (OTC) drugs on a case-by-case basis. There are between 100,000 and 500,000 of these products, few of which were previously

---

[4] Hearings on the Present Status of Competition in the Pharmaceutical Industry before the Subcommittee on Monopoly of the Senate Select Committee on Small Business, 92d Cong., 2d Sess., pt. 22, at 8525.

[5] Filings are due in June 1973. 37 Fed. Reg. 26432.

[6] S. Rep. No. 92–924, 92d Cong., 2d Sess., p. 2.

approved by FDA. In May 1972 FDA adopted a procedure for determining whether particular OTC products, not covered by NDAs are safe products, not ineffective, and not misbranded. 37 Fed. Reg. 9464. The procedure involves the establishment of independent expert panels for different categories of OTC drugs (*e. g.*, antacids, laxatives, analgesics) which would review all available data and prepare monographs prescribing drug composition, labeling, and manufacturing controls. OTCs conforming to the monograph will not be considered either misbranded or a "new drug" requiring an NDA. The regulation provides for a hearing before the expert panel, comments and rebuttal comments on the monograph and finally a hearing before the Commissioner and judicial review. *Id.*, at 9475.

This case, like the cross-petition in the *Hynson* case (72-414) raises the question whether FDA has authority to decide in an administrative hearing whether a drug satisfies the new effectiveness requirements of the Act. As noted, the Commissioner ordered that three NDAs for the drugs in question be withdrawn. Review order was not sought in the Court of Appeals as provided in § 505 (h), 21 U. S. C. § 355 (h). Rather, the aggrieved manufacturers of "me-too" drugs filed suit in the District Court, with the results we have already detailed. The narrow question is whether the FDA may decide whether a drug is a "new drug" on referral from a district court.

As already noted, an order denying an NDA and withdrawing one is reviewable by the Court of Appeals, § 505 (h); and we see no reason why Congress could not make one method of review the exclusive one. Certainly an order that does not deny or withdraw an NDA is reviewable under the Administrative Procedure Act, if it declares a "new drug" status. See *Hynson* cases, *ante*,

at —. In bolstering that conclusion we should note in passing that *Abbott Laboratories* v. *Gardner*, 387 U. S. 136, 144, said that the provisions stated in this Act for judicial review do not manifest "a congressional purpose to eliminate judicial review of other kinds of agency action." While § 505 (h) would appear to be the exclusive method of obtaining judicial review of FDA's order withdrawing an NDA covering the instant drugs, the Government apparently did not oppose the District Court's taking jurisdiction nor appeal from its action and presents no objection to the exercise by the courts of jurisdiction in this case. It does, however, strenuously oppose the conclusions reached by the Court of Appeals.

That court, in holding that FDA has no jurisdiction to determine the "new drug" status of a drug, stated that the question of "new drug" status is never presented when an application of a manufacturer for approval is filed. Parties, of course, cannot confer jurisdiction; only Congress can do so. The line sought to be drawn by the Court of Appeals is FDA action on NDAs pursuant to § 505 (d) and § 505 (e) on the one hand and the question of "new drug" determination on the other. We can discern no such jurisdictional line under the Act. The FDA, as already stated, may deny an NDA where there is a lack of "substantial evidence" of the drug's effectiveness, based as we have outlined on clinical investigation by experts. But the "new drug" definition under § 201 (p) encompasses a drug "not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use." Whether a particular drug is a "new drug," depends in part on the expert knowledge and experience of scientists based on controlled clinical experimentation and backed by substantial support in scientific literature. One function is not peculiar to

juidicial expertise, the other to administrative expertise. The two types of cases overlap and strongly suggest that Congress desired that the administrative agency make both kinds of determinations. Even where no such administrative determination has been made and the issue arises in a district court in enforcement proceedings, it would be commonplace for the court to await an appropriate administrative declaration before it acted. See *Myers* v. *Bethlehem Shipbuilding Corp.,* 303 U. S. 41, 50–51; *Federal Power Commission* v. *Louisiana Power & Light Co.,* 406 U. S. 621, 647. It may, of course, be true that in some cases general recognition that a drug is efficacious might be made without the kind of scientific support necessary to obtain approval of an NDA. But as we indicate in the *Hynson* cases, *ante,* at —, the reach of scientific inquiry under both § 505 (d) and under § 201 (p) is precisely the same.

We think that it is implicit in the regulatory scheme, not spelled out in *heac verba,* that FDA has jurisdiction to decide with administrative finality, subject to the types of judicial review provided, the "new drug" status of individual drugs or classes of drugs. The deluge of litigation that would follow if "me-too" drugs and OTC drugs had to receive *de novo* hearings in the courts would enure to the interests of manufacturers and merchants in drugs, but not to the interests of the public that Congress was anxious to protect by the 1962 amendments, as well as OTC drugs and drugs covered by the 1972 Act. We are told that FDA is incapable of handling a caseload of more than perhaps 10 or 15 *de novo* judicial proceedings in a year. Clearly, if FDA were required to litigate, on a case-by-case basis, the "new drug" status of each drug now marketed, the regulatory scheme of the Act would be severely undermined, if not totally destroyed. Moreover, a case-by-case approach is inherently unfair because it requires compliance by one

manufacturer while his competitors marketing similar drugs remain free to violate the Act. In a case much more clouded with doubts than this one, we held that we would not "in the absence of compelling evidence that such was Congress' intention . . . prohibit administrative action imperative for the achievement of an agency's ultimate purposes." *Permian Basin Area Rate Cases*, 390 U. S. 747, 780. And see *Ricci* v. *Chicago Mercantile Exchange*, 409 U. S. 289, 304–306.

We conclude that the District Court's referral of the "new drug" and the "grandfather" issues to FDA was appropriate, as these are the kinds of issues peculiarly suited to initial determination by the FDA. As the District Court said: "Evaluation of conflicting reports as to the reputation of drugs among experts in the field is not a matter well left to a court without chemical or medical background." — F. Supp., at —. The determination whether a drug is generally recognized as safe and effective within the meaning of § 201 (p)(1) necessarily implicates complex chemical and pharmacological considerations. Threshold questions within the peculiar expertise of an administrative agency are appropriately routed to the agency, while the court holds its hand. As we stated in *Far Eastern Conference* v. *United States*, 342 U. S. 570, 574–575: ". . . in cases raising issues of fact not within the conventional experience of judges or cases requiring the exercise of administrative discretion, agencies created by Congress for regulating the subject matters should not be passed over. This is so even though the facts after they have been appraised by specialized competence serve as a premise for legal consequences to be judicially defined. Uniformity and consistency in the regulation of business entrusted to a particular agency are secured, and the limited functions of review by the judiciary are more rationally exercised, by preliminary resort for ascertaining and interpreting the circumstances

underlying legal issues to agencies that are better equipped than courts by specialization, by insight gained through experience, and by more flexible procedure." And see *Port of Boston Marine Terminal Association* v. *Rederiaktubolaget Transatlantic*, 400 U. S. 62, 68; *Ricci* v. *Chicago Mercantile Exchange*, *supra*, at 304–306.

*Reversed.*

MR. JUSTICE BRENNAN took no part in the consideration or decision of this case. MR. JUSTICE STEWART took no part in the decision of this case.

Slip Opinion

NOTE: Where it is feasible, a syllabus (headnote) will be released, as is being done in connection with this case, at the time the opinion is issued. The syllabus constitutes no part of the opinion of the Court but has been prepared by the Reporter of Decisions for the convenience of the reader. See *United States v. Detroit Lumber Co.*, 200 U.S. 321, 337.

# SUPREME COURT OF THE UNITED STATES

Syllabus

## USV PHARMACEUTICAL CORP. *v.* WEINBERGER ET AL.

CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

No. 72-666. Argued April 17, 1973—Decided June 18, 1973

Petitioner sells drug products containing citrus bioflavonoid, an extract from fruit skins, as a principal active ingredient. In the 1950's new drug applications (NDA's) were filed and became effective for seven products, and two were sold without any NDA. After the enactment of the 1962 amendments to the Federal Food, Drug, and Cosmetic Act, these products, together with a large number of other bioflavonoid products were examined by the Food and Drug Administration for effectiveness. Based upon NAS-NRC reports and its own evaluation, FDA gave notice of opportunity for hearing on its proposal to withdraw approvals of NDA's for all drugs containing these compounds, alone or in combination with other drugs. Petitioner then brought suit in the District Court, seeking a declaratory judgment that its drugs are exempt from the efficacy requirements under § 107 (c)(4), the so-called "grandfather" clause. The FDA refused a stay pending the judicial proceedings and went forward with its administrative action. Petitioner submitted no evidence of "adequate and well-controlled investigations" as required by § 505 (d) to support its claims of effectiveness, and the FDA withdrew petitioner's NDA's. Section 107 (c)(4) exempts from the effectiveness requirements any drug which on the day preceding the 1962 enactment (1) was commercially used or sold in the United States, (2) was not a "new drug" as defined in the 1938 Act, and (3) "was not covered by an effective application" for a new drug under the 1938 Act. The District Court found that two of the products had never been covered by effective NDA's and that, while seven had been covered, their applications had later been withdrawn by petitioner. It concluded that petitioner's drugs were not covered by effective applications, and hence were exempt from the

Syllabus

effectiveness criterion. The Court of Appeals reversed on the merits. It held that petitioner's drugs were not entitled to an exemption, that an applicant could not withdraw an NDA once it became effective, that the drugs were "covered by an effective application," and that although "me-too" drugs (similar drugs) of other manufacturers would be exempt, petitioner's "me-toos" were not exempt. *Held:*

1. "Any drug" is used in § 107 (c)(4) in the generic sense, which means that the "me-toos" whether the products of the same or of different manufacturers "covered" by an "effective" NDA are not exempt from the efficacy requirement of § 201 (p). Pp. 7–9.

2. Prescription drugs on the market are subject to the 1962 efficacy requirements, for if the 1962 amendments are to be comprehensively meaningful, § 107 (c)(4) cannot be read so as to provide a loophole to permit the marketing of drugs previously subject to new drug regulation without demonstrating by the new statutory standards that they have the claimed efficacy. Pp. 9–10.

3. The congressional purpose was to exempt only those drugs that never had been subject to the drug regulation, and therefore any drug for which an NDA had once been effective does not fall within the exempt category. Pp. 10–11.

461 F. 2d 223, affirmed.

DOUGLAS, J., delivered the opinion of the Court, in which all Members joined, except BRENNAN, J., who took no part in the consideration or decision of the case, and STEWART, J., who took no part in the decision of the case.

# SUPREME COURT OF THE UNITED STATES

No. 72-666

| | |
|---|---|
| USV Pharmaceutical Corporation, Petitioner, *v.* Caspar W. Weinberger, Secretary of Health, Education, and Welfare, et al. | On Writ of Certiorari to the United States Court of Appeals for the Fourth Circuit. |

[June 18, 1973]

MR. JUSTICE DOUGLAS delivered the opinion of the Court.

Petitioner sells a line of drugs containing citrus bioflavonoid as a principal active ingredient which is an extract from fruit skins. The drugs are sold in capsules, syrup, and tablets. In the 1950s NDAs were filed and became effective for seven of them; two, however, were sold without any NDA. In 1961 FDA advised petitioner that two of the products, when distributed under the existing labels, were not new drugs. These drugs were recommended for a wide variety of ailments from bleeding to hypertension to ulcerative colitis. After the 1962 amendments these products, together with a large number of other bioflavonoid products, were examined by FDA for drug effectiveness. NAS-NRC panels reviewed them. One panel on Metabolic Disorders concluded that the "use of these materials as hemostatic agents for capillary fragility is felt to be unjustifiable and not proved." A panel on Hematologic Disorders found there was no proof that these products were efficacious for any medical use.

Based upon the NAS-NRC reports and its own evaluation, FDA gave notice of opportunity for hearing on its

proposal to withdraw approvals of NDAs for all drugs containing these compounds, alone or in combination with other drugs. Petitioner thereupon brought suit in the District Court, asking for a declaratory judgment that its drugs are exempt from the efficacy requirements under § 107 (c)(4). The administrative proceedings went forward, FDA refusing a stay pending the judicial proceedings. Petitioner submitted no evidence of "adequate and well-controlled investigations" as required by § 505 (d) of the Act to support its claims of effectiveness. The Commissioner made findings and withdrew petitioner's NDAs.

In the District Court the petitioner contended that the drugs were exempt from regulation by reason of § 107 (c)(4) of the 1962 amendments which provides:

> "In the case of any drug which, on the day immediately preceding the enactment date, (A) was commercially used or sold in the United States, (B) was not a new drug as defined by section 201(p) of the basic Act as then in force, and (C) was not covered by an effective application under section 505 of that Act, the amendments to section 201 (p) made by this Act shall not apply to such drug when intended solely for use under conditions prescribed, recommended, or suggested in labeling with respect to such drug on that day."

The District Court found that two of the products had never been covered by effective NDAs and that, while seven had been covered, their applications had later been withdrawn by petitioner. It found that the products were "safe" for use in treating abnormal capillary permeability and fragility. It therefore concluded that, as of the day the 1962 amendments became effective, petitioner's products were not new drugs, were not covered by effective applications within the meaning of § 107 (c)

(4), and hence were exempt from the effectiveness criterion added to the regulatory provisions of §§ 505 and 201 (p). In so ruling, the District Court necessarily determined that it, and not the Food and Drug Administration, had jurisdiction to decide exemption questions. — F. Supp. —.

The Court of Appeals agreed that the District Court alone had jurisdiction and reversed on the merits.[1] 461 F. 2d 223. It held that none of petitioner's bioflavoinoid drugs were entitled to exemption under § 107 (c)(4). As to the seven for which NDAs had been filed, it held that an applicant could not withdraw an NDA once it became effective. It concluded that even if the drugs were generally recognized as safe on the day preceding the effective date of the 1962 Act, they were "covered by an effective application" within the meaning of § 107 (c)(4) (C) and thus were not exempt from the 1962 amendments. As to the "me-too" drugs, those specific drugs for which petitioner had not filed an NDA, the Court of Appeals held that although the "me-toos" of other manufacturers competing with petitioner's bioflavonoids would be exempt, petitioner's "me-toos" were not exempt

[1] Unlike the situation in *CIBA Corp.* v. *Weinberger, ante,* at —, the order of the Commissioner withdrawing petitioner's NDAs had not become final prior to the District Court assuming jurisdiction. In fact, the Court of Appeals for the District of Columbia Circuit reversed the Commissioner's decision, 466 F. 2d 455, and the proceedings on remand are now pending before the Commission. Thus, petitioner was not barred from proceeding in the District Court. Cf. *CIBA Corp.* v. *Weinberger, supra.* Our decision today is not meant to indicate that the District Court, had it concluded that its jurisdiction was concurrent with that of FDA, would not have abused its discretion in refusing to stay this action pending the outcome of administrative proceedings. Cf. *Weinberger* v. *Bentex Pharmaceuticals, Inc., ante,* at —. The Court of Appeals below found it unnecessary to consider whether petitioner had failed to exhaust its administrative remedies. 461 F. 2d, at 226.

because the NDAs covering the pioneer drugs prepared by petitioner covered all of its products similar in formula and labeling. While the Government agrees that petitioner's "me-too" products should be accorded the same treatment as the "me-toos" of other manufacturers who had never filed NDAs, the parties are at odds on other issues.[2]

The resolution of the questions presented turns essentially on the meaning of § 107 (c)(4), quoted above. But as background for the problem of construction, references should be made to other 1962 amendments. Section 201 (p)[3] was amended to redefine a "new drug" as one not generally recognized by experts as both safe and effective for use under the conditions prescribed or one that has not been used to a material extent and

[2] There lurks in the case a question whether a drug could have been unsafe prior to the 1962 amendments because it was ineffective in treating the conditions for which its use was recommended by the label. That question, however, was not presented in the petition for certiorari.

[3] "The term 'new drug' means—

"(1) Any drug (except a new animal drug or an animal feed bearing or containing a new animal drug) the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof, except that such a drug not so recognized shall not be deemed to be a 'new drug' if at any time prior to the enactment of this Act it was subject to the Food and Drugs Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use; or

"(2) Any drug (except a new animal drug or an animal feed bearing or containing a new animal drug) the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions."

for a material time. Section 505 (a) was amended to require affirmative approval of FDA, where previously it had provided that an NDA would automatically become effective unless a contrary order were issued.[4] Section 505 (d) [5] was amended to require disapproval of an appli-

[4] Section 505 (c) provides:

"Within one hundred and eighty days after the filing of an application under this subsection, or such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall either—

"(1) approve the application if he then finds that none of the grounds for denying approval specified in subsection (d) applies, or

"(2) give the applicant notice of an opportunity for a hearing before the Secretary under subsection (d) on the question whether such application is approvable. If the applicant elects to accept the opportunity for hearing by written request within thirty days after such notice, such hearing shall commence not more than ninety days after the expiration of such thirty days unless the Secretary and the applicant otherwise agree. Any such hearing shall thereafter be conducted on an expedited basis and the Secretary's order thereon shall be issued within ninety days after the date fixed by the Secretary for filing final briefs.

[5] That section provides:

"If the Secretary finds, after due notice to the applicant in accordance with subsection (c) and giving him an opportunity for a hearing, in accordance with said subsection, that (1) the investigations, reports of which are required to be submitted to the Secretary pursuant to subsection (b), do not include adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof; (2) the results of such tests show that such drug is unsafe for use under such conditions or do not show that such drug is safe for use under such conditions; (3) the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to preserve its identity, strength, quality, and purity; (4) upon the basis of the information submitted to him as part of the application, or upon the basis of any other information before him with respect to such drug, he has insufficient information to determine whether such drug is safe for use under such conditions; or (5) evaluated on the basis of the information submitted to him

cation if there is "a lack of substantial evidence that the drug will have the effect it purports or is represented to have." Section 505 (e) was amended to require that any previous approval of an application be withdrawn whenever it appears from new information or otherwise that there is a lack of substantial evidence of the drug's effectiveness.

There remained the problem of the application of the new drug efficacy provisions to drugs already on the market. Without transitional protection all drugs—except those marketed prior to the 1938 Act whose labeling had not been changed and which were exempt from the "new drug" provision of § 210 (p)—would have been in violation of the amended Act unless generally recognized as effective. Even NDAs which were outstanding would have become ineffective because FDA had not approved them under the new criteria. Section 107 (c) (2) of the amendments therefore provides that applications which were effective on the day before the enactment date of the 1962 amendments should be deemed

as part of the application and any other information before him with respect to such drug, there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof; or (6) based on a fair evaluation of all material facts, such labeling is false or misleading in any particular; he shall issue an order refusing to approve the application. If, after such notice and opportunity for hearing, the Secretary finds that clauses (1) through (6) do not apply, he shall issue an order approving the application. As used in this subsection and subsection (e) the term 'substantial evidence' means evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is presented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof."

"approved." Section 107 (c)(2) thus eliminated the necessity to review and approve every application already on file.

Section 107 (c)(3) provides that drugs covered by NDAs already on file whose labeling remains unchanged are not affected by the amended provisions of § 505 (b) or by approvals or refusals under § 505 (d) insofar as the effectiveness of the drugs is concerned, so long as the application is not withdrawn or suspended under § 505 (e). It also provides that the new effectiveness requirement in the withdrawal provision would not apply until two years after the amendments were adopted, or until the NDA approval were withdrawn for reasons other than lack of the drug's effectiveness, whichever came first. It seems apparent that by reason of § 107 (c)(3) the industry was assured it could continue to market previously approved NDAs unless and until the NDA was withdrawn and that before such withdrawal they would be given a minimum of two years within which to submit "substantial evidence" to support the claims for their products.

Section 107 (c)(4) exempted drugs from the new effectiveness requirements so long as their composition and labeling remained unchanged. This exemption, however, applies only to a product that, on the day before the 1962 amendments became effective, (A) was used or sold commercially in the United States, (B) was generally recognized by the experts as safe; and (C) was not "covered" by an "effective" application.

The first question is, which "me-too" copies of an NDA drug are subject to the efficacy requirements to the same extent as the NDA product itself? Are only the "me-toos" of the same manufacturer "covered" by an effective application within the meaning of § 107 (c)(4)(C) and thus not exempt from § 201 (p) or are no "me-toos" exempt whoever manufactures them? It seems clear

that § 107 (c) was designed in general to make the new 1962 requirements applicable to drugs then on the market after a two-year grace period. Section 107 (c)(4) created an exception from this general policy. Senator Eastland explained these "transitional provisions," stating:[6] "Established drugs which have never been required to go through new drug procedures will not be affected by the new effectiveness test insofar as their existing clauses are concerned." It is true that an NDA covers a particular product or products that it names and that § 505 when applied to an NDA is personal to the manufacturer who files it. Section 505, in other words, addresses itself to drugs as individual products. But we agree with the Government that "any drug" when used in § 107 (c)(4) is used in the generic sense, which means that the "me-toos" whether products of the same or of different manufacturers "covered" by an "effective" NDA are not exempt from the efficacy requirements of § 201 (p). If that were not true, then, as the Court of Appeals said, the "me-toos" of one manufacturer covered by an NDA of another manufacturer would be exempt from regulation, while the "me-toos" of the manufacturer holding the NDA could be regulated. That seems to be a reading of § 107 (c)(4) that is discriminatory and needlessly so. For it is avoided by taking "any drug" in that subsection as a generic term. The transitional nature of § 107 (c) works in that direction. A reading to exclude all "me-too" drugs from the word "covered" as used in § 107 (c)(4) would create an hiatus in the regulatory scheme for which there seems to be no cogent reason. We find no persuasive reason to resolve the ambiguities in favor of the manufacturers so that pre-existing pioneer drugs would be subject to the new efficacy requirements but the "me-toos" which often do equal service for them would escape

[6] 108 Cong. Rec. 17366.

the thrust of the 1962 amendments. That resolution of the ambiguities would largely leave pre-1962 drugs of unproved effectiveness untouched by the 1962 amendments and perpetuate a competitive contest in the marketing of ineffective pre-1962 drugs. FDA would, of course, have authority to pursue that category of drugs under the misbranding provisions of the Act. But that slow cumbersome method is utterly unsuited to the need. We decline to attribute such a self-defeating purpose to the Congress. After all, the 1962 regulatory scheme proposes administrative control through an expert agency in lieu of the more cumbersome 1938 devices, as a result of which, "good medical practice is hampered, and the consumer is misled until, perhaps years later, the Government has gathered the necessary evidence to sustain its burden of proving the violation in court."[7]

Petitioner, focusing on prescription drugs,[8] contends that the construction of § 107 (c)(4) urged by the Government would make the exemption meaningless. Prescription drugs, as FDA points out, are not likely to have come on the market subsequent to 1938 without being a "new drug" for some time. But the OTC drugs, known as the proprietaries, are often made up of old, established ingredients. Such products, coming on the market for the first time between 1938 and 1962, might never have been subject to new drug regulation. If so, they would be entitled to the exemption provided by § 107 (c)(4). Senator Kefauver, the main sponsor of the 1962 Act, deplored the absence in an earlier bill of the

---

[7] H. R. Rep. No. 2464, 87th Cong., 2d Sess., at 3.

[8] Prescription drugs, as defined by § 503 (b), 21 U. S. C. § 353 (b), include any drug for human use which (A) is habit-forming; (B) "because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe except under the professional supervision of a practitioner licensed by law to administer such drug"; or (C) is limited to prescription used in the application under § 505.

failure to submit proprietaries on the market to tests of efficacy. He said: [9]

> "Effectiveness, as well as safety, should apply to new proprietary drugs, but proprietaries now on the market are not to be subject under the present bill to the provisions requiring them, upon notice by the FOA (*sic*), to support their claims for effectiveness. I think they should be so required. That is a matter which can be remedied in conference or by other legislation."

It can be inferred from this statement that prescription drugs on the market were to be subjected to the efficacy requirements. If the 1962 amendments are to be comprehensively meaningful, we decline to read § 107 (c) (4) so as to provide a loophole so that the manufacturers can go on marketing drugs previously subject to new drug regulation without demonstrating by the new statutory standards that they are effective as claimed.

The second question presented by this case is whether an applicant could have withdrawn or "deactivated" an NDA prior to the 1962 amendments so that its drug was no longer "covered by an effective application" and thus is now exempt from efficacy regulation by reason of § 107 (c)(4). Petitioner in 1961 had stated in a letter to the Director of New Drug Branch of the Bureau of Medicine in FDA that "[i]t is our recollection that the C. V. P. class of products were no longer considered to be new drugs . . . ." Petitioner in 1961 also stopped filing supplemental information as required by regulation with regard to the products for which NDAs had become effective. It claims that these acts were sufficient to withdraw the NDAs and to bring its products within the exemption.

---

[9] 108 Cong. Rec. 17368.

Initially, we repeat that the legislative history indicates that it was Congress' purpose to exempt only those drugs that never had been subject to the new drug regulation.[10] Quite obviously, any drug for which an NDA once had been effective does not fall within that category.

Congress rejected an approach that would have exempted from the efficacy reqirements of the 1962 amendments all drugs then marketed which had become generally recognized as safe. It now would be irrational for us to construe § 107 (c)(4) of the amendments to exempt a drug merely because the manufacturer had taken some formal steps totally unrelated to the drug's effectiveness to indicate that the drug was no longer a "new drug" under the pre-1962 standards. The result would be that some drugs for which an NDA had been filed would be subject to the efficacy requirements and some would not, even though one could not differentiate between the drugs on the grounds of effectiveness. For example, 43 NDAs had been filed with respect to bioflavonoids and related compounds. There is no reason to believe that any product is more or less effective than another. According to the Solicitor General, the "state of activity, inactivity, or withdrawal" of the applications varied from one to the next when the 1962 amendments became effective. It would be totally inconsistent with the statutory scheme and the policy underlying the 1962 amendments, as well as patently unjust, to conclude that some manufacturers could continue to market their bioflavonoid products, but others could not. We cannot attribute such an intention to Congress and, accordingly, cannot agree with petitioner that its NDAs had been withdrawn prior

---

[10] See S. Rep. No. 1744, 87th Cong., 2d Sess., pt. 2, at 8; H. R. Rep. No. 2464, 87th Cong., 2d Sess., 12; H. R. Rep. No. 2526, 87th Cong., 2d Sess., 22–23; 108 Cong. Rec. 17366.

to 1962 so that its bioflavonoid products were no longer "covered by an effective application."

*Affirmed.*

MR. JUSTICE BRENNAN took no part in the consideration or decision of this case. MR. JUSTICE STEWART took no part in this decision.